PHYSICIAN LABELING

Tachos DR – Atrial Tx

Implantable Cardioverter Defibrillator

Technical Manual

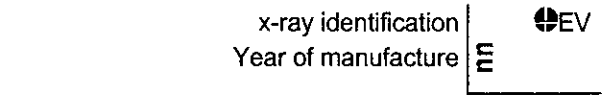
BIOTRONIK

Tachos DR - Atrial Tx

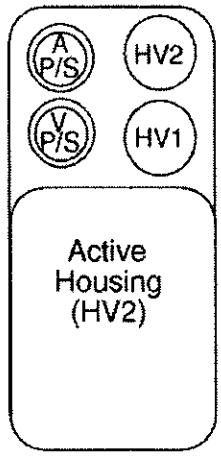
Implantable Cardioverter Defibrillator

x-ray Identification

Inside the housing, top right-hand side:



Contents



A P/S = Atrial pace/sense port

V P/S = Ventricular pace/sense port

HV2 = Vena Cava Defib. port or Blind Plug

HV1 = Ventricular Defib port

Tachos DR - Atrial Tx Specifications

Model:	
1st Battery Voltage:	6.3 Volts
2nd Battery Voltage:	2.8 Volts
Maximum Shock Energy:	30 joules
Defibrillation Lead Ports	Two DF-1 (3.2 mm)
Pacing Lead Ports	Two IS-1 (3.2 mm)
Dimension:	67 x 57 x 15 mm
Volume:	48 cc
Mass:	84 g

Tachos DR - Atrial Tx Description

Housing Material:	Titanium
Header Material:	Epoxy Resin
Sealing Plug Material:	Silicone
1st Battery Material	Li / MnO_2
2nd Battery Material	Li/I

1. General

1.1 System Description

The Tachos DR - Atrial Tx is a dual chamber implantable cardioverter defibrillator (ICD) that detects and treats atrial and ventricular tachyarrhythmias and provides dual chamber rate adaptive bradycardia pacing support. The ICD uses atrial and ventricular sensing/pacing leads to provide enhanced atrial and ventricular tachyarrhythmia discrimination through BIOTRONIK's SMART Detection^{TM} algorithm. The ICD is designed to collect diagnostic data to aid the physician's assessment of a patient's condition and the performance of the implanted device.

The Tachos DR - Atrial Tx provides therapy for atrial and ventricular tachyarrhythmias with a complete range of programmable antitachycardia pacing (ATP), high frequency burst, and/or defibrillation therapy. The shock polarity and energy may be programmed to tailor the therapy to appropriately treat each patient's tachyarrhythmias. The ICD provides biphasic shocks with programmable energies from 1.0 to 30 joules.

The Tachos DR - Atrial Tx has two DF-1 defibrillation/ cardioversion and two IS-1 pacing/sensing header ports. IS-1 refers to the international standard whereby leads and generators from different manufacturers are assured a basic fit [Reference ISO 5841-3:1992]. DF-1 refers to the international standard for defibrillation lead connectors [Reference ISO 11318:1993].

External devices that interact with and test the implantable devices are also part of the ICD System. These external devices include the TMS 1000 ^{PLUS} Tachyarrhythmia Monitoring System and the EPR 1000 ^{PLUS} Programming and Monitoring System. These programmers are used to interrogate and program the ICD.

1.2 Indications and Usage

The Tachos DR - Atrial Tx Implantable Cardioverter Defibrillator (ICD) is intended to provide ventricular antitachycardia pacing and ventricular defibrillation, for automated treatment of life-threatening ventricular arrhythmias.

The device is indicated for use in ICD patients with either atrial tachyarrhythmias or who are at risk of developing atrial tachyarrhythmias.

1.3 Contraindications

Do not use the Tachos DR - Atrial Tx Implantable Cardioverter Defibrillator (ICD) in patients:

- Whose ventricular tachyarrhythmias may have transient or reversible causes including:
  - acute myocardial infarction
  - digitalis intoxication
  - drowning
  - electrocution
  - electrolyte imbalance
  - sepsis
  - hypoxia or other causes of transient arrhythmias (e.g., electrocution)
- Patients with incessant VT of VF
- Patients with unipolar pacemaker
- Patients whose only disorder is bradyarrhythmia or atrial arrhythmia

1.4 Warnings and Precautions

MRI (Magnetic Resonance Imaging) - Do not expose a patient to MRI device scanning. Strong magnetic fields may damage the device and cause injury to the patient.

Electrical Isolation - To prevent inadvertent arrhythmia induction, electrically isolate the patient during the implant procedure from potentially hazardous leakage currents.

Lead Systems - The use of another manufacturer's ICD lead system may cause potential adverse consequences such as undersensing of cardiac activity and failure to deliver necessary therapy.

Resuscitation Availability - Do not perform induction testing unless an alternate source of patient defibrillation such as an external defibrillator is readily available. In order to implant the ICD system, it is necessary to induce and convert the patient's ventricular tachyarrhythmias.

Unwanted Shocks – Always program the therapy status to DISABLED prior to handling the device to prevent the delivery of serious shocks to the patient or the person handling the device during the implant procedure.

Rate-Adaptive Pacing – Use rate-adaptive pacing with care in patients unable to tolerate increased pacing rates.

1.4.1 Sterilization, Storage, and Handling

Device Packaging - Do not use the device if the device's packaging is wet, punctured, opened or damaged because the integrity of the sterile packaging may be compromised. Return the device to BIOTRONIK.

Re-sterilization - Do not re-sterilize and re-implant explanted devices.

Storage (temperature) - Store the device between 5° to 55°C (41° - 131° F) because temperatures outside this range could damage the device.

Storage (magnets) - To avoid damage to the device, store the device in a clean area, away from magnets, kits containing magnets, and sources of electromagnetic interference (EMI).

Temperature Stabilization - Allow the device to reach room temperature before programming or implanting the device because temperature extremes may affect initial device function.

Use Before Date - Do not implant the device after the USE BEFORE DATE because the device may have reduced longevity.

1.4.2 Device Implantation and Programming

Blind Plug - A blind plug must be inserted and firmly connected into any unused header port to prevent chronic fluid influx and possible shunting of high energy therapy.

Capacitor Reformation - Infrequent charging of the high voltage capacitors may extend the charge times of the ICD. The capacitors may be reformed manually, or the ICD may be programmed to reform the capacitors automatically. For further information, please refer to Section 2.7.2 Capacitor Reforming.

Connector Compatibility - ICD and lead system compatibility should be confirmed prior to the implant procedure. Consult your BIOTRONIK representative regarding lead/pulse generator compatibility prior to the implantation of an ICD system. For further information, please refer to **Appendix A**.

ERI (Elective Replacement Indicator) - Upon reaching ERI, the battery has sufficient energy remaining to continue monitoring for at least three months and to deliver a minimum of six 30 joule shocks. After this period, all tachyarrhythmia detection and therapy is disabled. Bradycardia functions are still active at programmed values until the voltage of the 6.3 volt battery drops below 3.0 volts.

Magnets - Positioning of a magnet or the programming wand over the ICD will suspend tachycardia detection and treatment. The minimum magnet strength required to suspend tachycardia treatment is 1.8 mT. When the magnet strength decreases to less than 1 mT, the reed contact is reopened.

Pacemaker/ICD Interaction - In situations where an ICD and a pacemaker are implanted in the same patient, interaction testing should be completed. If the interaction between the ICD and the pacemaker cannot be resolved through repositioning of the leads or reprogramming of either the pacemaker or the ICD, the pacemaker should not be implanted (or explanted if previously implanted).

Programmed Parameters – Program the device parameters to appropriate values based on the patient's specific arrhythmias and condition.

Programmers - Use only BIOTRONIK programmers to communicate with the device (TMS 1000 ^{PLUS}, or EPR 1000 ^{PLUS}).

Sealing System - Failure to properly insert the torque wrench into the perforation at an angle perpendicular to the connector receptacle may result in damage to the sealing system and its self-sealing properties.

Defibrillation Threshold - Be aware that the changes in the patient's condition, drug regimen, and other factors may change the defibrillation threshold (DFT) which may result in non-conversion of the arrhythmia post-operatively. Successful conversion of ventricular fibrillation or ventricular tachycardia during arrhythmia conversion testing is no assurance that conversion will occur post-operatively.

Manual Shocks – User-commanded shocks may be withheld if the ICD is already busy processing a manual command or the Battery Status is low.

Charge Time - When preparing a high energy shock the charge circuit stops charging the capacitors after 20 seconds, and delivers the stored energy as shock therapy. After the device reaches ERI the stored energy may be less than 30 joules per shock.

Shock Impedance - If the shock impedance is less than twenty-five ohms, reposition the lead system to allow a greater distance between the electrodes. Never implant the device with a lead system that has measured shock impedance as less than twenty-five ohms. Damage to the device may result.

1.4.3 Lead Evaluation and Connection

Capping Leads - If a lead is abandoned rather than removed, it must be capped to ensure that it is not a pathway for currents to or from the heart.

Gripping Leads - Do not grip the lead with surgical instruments or use excessive force or surgical instruments to insert a stylet into a lead.

Kinking Leads - Do not kink leads. This may cause additional stress on the leads that can result in damage to the lead.

Liquid Immersion - Do not immerse leads in mineral oil, silicone oil, or any other liquid.

Short Circuit - Ensure that none of the lead electrodes are in contact (a short circuit) during delivery of shock therapy as this may cause current to bypass the heart or cause damage to the ICD system.

Straight Atrial Leads - When using a straight atrial lead e.g. non-preformed "J", a 1-month waiting period is recommended prior to programming atrial HF Burst therapy. This important consideration is related to the increased likelihood of atrial lead dislodgement during the first month after implant. A dislodged straight atrial lead could potentially fall in the ventricle and could subsequently result in the delivery of an undesired ventricular HF burst.

Far-field sensing of signals from the atrium in the ventricular channel or ventricular signals in the atrial channel should be avoided by appropriate lead placement, programming of pacing/sensing parameters, and maximum sensitivity settings. If it is necessary to lengthen A BLANK-V PACE or A BLANK-V SENSE, the parameter should be lengthened only long enough to eliminate far-field sensing as evidenced on the IEGMs. Extending either parameter unnecessarily may cause undersensing of actual atrial or ventricular events.

Suturing Leads - Do not suture directly over the lead body as this may cause structural damage. Use the appropriate suture sleeve to immobilize the lead and protect it against damage from ligatures.

Tricuspid Valve Bioprothesis - Use ventricular transvenous leads with caution in patients with a tricuspid valvular bioprosthesis.

Setscrew Adjustment – Back-off the setscrew(s) prior to insertion of lead connector(s) as failure to do so may result in damage to the lead(s), and/or difficulty connecting lead(s).

Cross Threading Setscrew(s) – To prevent cross threading the setscrew(s), do not back the setscrew(s) completely out of the threaded hole. Leave the torque wrench in the slot of the setscrew(s) while the lead is inserted.

Tightening Setscrew(s) – Do not overtighten the setscrew(s). Use only the BIOTRONIK supplied torque wrench.

Sealing System – Be sure to properly insert the torque wrench into the perforation at an angle perpendicular to the connector receptacle. Failure to do so may result in damage to the plug and its self-sealing properties.

1.4.4 Follow-up Testing

Defibrillation Threshold - Be aware that changes in the patient's condition, drug regimen, and other factors may change the defibrillation threshold (DFT), which may result in non-conversion of the arrhythmia post-operatively. Successful conversion of ventricular fibrillation or ventricular tachycardia during arrhythmia conversion testing is no assurance that conversion will occur post-operatively.

Resuscitation Availability - Ensure that an external defibrillator, and medical personnel, skilled in cardiopulmonary resuscitation (CPR), are present during post-implant device testing, should the patient require external rescue.

Safe Program – Within the EP Test screen, pressing the "Safe Program" key on the programmer head does not immediately send the safe program to the ICD. Pressing the "Safe Program" key activates the emergency function screen, but an additional screen touch is required to send the safe program to the ICD.

1.4.5 Pulse Generator Explant and Disposal

Device Incineration - Never incinerate the ICD due to the potential for explosion. The ICD must be explanted prior to cremation.

Explanted Devices - Return all explanted devices to BIOTRONIK.

Unwanted Shocks – Always program the therapy status to DISABLED prior to handling the device to prevent the delivery of serious shocks to the patient or the person handling the device during the implant procedure.

1.4.6 Hospital and Medical Hazards

Electromagnetic interference (EMI) signals present in hospital and medical environments may affect the function of any ICD or pacemaker. The ICD is designed to selectively filter out EMI noise. However, due to the variety of EMI signals, absolute protection from EMI is not possible with this or any other ICD.

The ICD system should be checked after any of the following medical procedures:

Diathermy - Diathermy therapy is not recommended for ICD patients due to possible heating effects of the pulse generator and at the implant site. If diathermy therapy must be used, it should not be applied in the immediate vicinity of the pulse generator or lead system.

Electrocautery - Electrosurgical cautery could induce ventricular arrhythmias and/or fibrillation, or may cause device malfunction or damage. If use of electrocautery is necessary, the current path and ground plate should be kept as far away from the pulse generator and leads as possible (at least 6 inches (15 cm)).

External Defibrillation - The device is protected against energy normally encountered from external defibrillation. However, any implanted device may be damaged by external defibrillation procedures. In addition, external defibrillation may also result in permanent myocardial damage at the electrode-tissue interface as well as temporary or permanent elevated pacing thresholds. When possible, observe the following precautions:

- Position the adhesive electrodes or defibrillation paddles of the external defibrillator anterior-posterior or along a line perpendicular to the axis formed by the implanted device and the heart.
- Set the energy to a level not higher than is required to achieve defibrillation.
- Place the paddles as far as possible away from the implanted device and lead system.
- After delivery of an external defibrillation shock, interrogate the ICD to confirm device status and proper function.

Lithotripsy - Lithotripsy may damage the ICD. If lithotripsy must be used, avoid focusing near the ICD implant site.

MRI (Magnetic Resonance Imaging) - Do not expose a patient to MRI device scanning. Strong magnetic fields may damage the device and cause injury to the patient.

Radiation - High radiation sources such as cobalt 60 or gamma radiation should not be directed at the pulse generator. If a patient requires radiation therapy in the vicinity of the pulse generator, place lead shielding over the device to prevent radiation damage and confirm its function after treatment.

RF Ablation - Prior to performing an ablation procedure, deactivate the ICD during the procedure. Avoid applying ablation energy near the implanted lead system whenever possible.

1.4.7 Home and Occupational Hazards

Patients should be directed to avoid devices that generate strong electromagnetic interference (EMI) or magnetic fields. EMI could cause device malfunction or damage resulting in non-detection or delivery of unneeded therapy. Moving away from the source or turning it off will usually allow the ICD to return to its normal mode of operation.

The following equipment (and similar devices) may affect normal ICD operation: electric arc or resistance welders, electric melting furnaces, radio/television and radar transmitters, power-generating facilities, high-voltage transmission lines, and electrical ignition systems (of gasoline-powered devices) if protective hoods, shrouds, etc., are removed.

1.4.8 Cellular Phones

Testing has indicated there may be a potential interaction between analog cellular phones and BIOTRONIK ICD systems. Potential effects may be due to either the analog cellular phone signal or the magnet within the telephone and may include inhibition of therapy when the telephone is within 6.0 inches (15 cm) of the ICD, when the ICD is programmed to standard sensitivity.

Patients having an implanted BIOTRONIK ICD who operate an analog cellular telephone should:

- Maintain a minimum separation of 6.0 inches (15 cm) between a hand-held personal cellular telephone and the implanted device.
- Set the telephone to the lowest available power setting, if possible.
- Patients should hold the phone to the ear opposite the side of the implanted device. Patients should not carry the telephone in a breast pocket or on a belt over or within 6.0 inches (15 cm) of the implanted device as some telephones emit signals when they are turned ON, but not in use (i.e., in the listen or stand-by mode). Store the telephone in a location opposite the side of implant.

Based on results to date, adverse effects resulting from interactions between cellular telephones and implanted ICDs have been transitory. The potential adverse effects could include inhibition or delivery of additional therapies. If electromagnetic interference (EMI) emitting from a telephone does adversely affect an implanted ICD, moving the telephone away from the immediate vicinity of the ICD should restore normal operation. A recommendation to address every specific interaction of EMI with implanted ICDs is not possible due to the disparate nature of EMI.

1.4.9 Electronic Article Surveillance (EAS)

Equipment such as retail theft prevention systems may interact with pulse generators. Patients should be advised to walk directly through and not to remain near an EAS system longer than necessary.

1.4.10 Home Appliances

Home appliances normally do not affect ICD operation if the appliances are in proper working condition and correctly grounded and shielded. There have been reports of the interaction of electric tools or other external devices (e.g. electric drills, older models of microwave ovens, electric razors, etc.) with ICDs when they are placed in close proximity to the device.

1.5 Adverse Effects

1.5.1 Potential Adverse Effects

The following is a list of the potential risks that may occur with this device:

- Acceleration of arrhythmias
- Air embolism
- Bleeding
- Chronic nerve damage
- Erosion
- Excessive fibrotic tissue growth
- Extrusion
- Fluid accumulation
- Formation of hematomas or cysts
- Inappropriate shocks
- Infection
- Keloid formation
- Lead abrasion and discontinuity
- Lead migration/dislodgment
- Myocardial damage
- Pneumothorax
- Shunting current or insulating myocardium during defibrillation with internal or external paddles
- Potential mortality due to inability to defibrillate or pace
- Thromboemboli
- Venous occlusion
- Venous or cardiac perforation
- Additionally, the potential risks related to the atrial therapy feature of this ICD system, may include the following:
- Induction of ventricular arrhythmias

- Acceleration of atrial arrhythmias
- Inappropriate atrial shocks
- Potential morbidity related to ineffective atrial shocks

Patients susceptible to frequent shocks despite antiarrhythmic medical management may develop psychological intolerance to an ICD system that may include the following:

- Dependency
- Depression
- Fear of premature battery depletion
- Fear of shocking while conscious
- Fear that shocking capability may be lost
- Imagined shocking (phantom shock)

There may be other risks associated with this device that are currently unforeseeable.

1.5.2 Reported Adverse Events

The multi-center, non-randomized clinical investigation was designed to demonstrate the effectiveness of the Tachos DR - Atrial Tx to detect and convert atrial tachyarrhythmias in patients that require standard ICD therapy and that have a history or significant risk of atrial tachyarrhythmias.

Table 1 provides a summary of the adverse events that were reported during the clinical study regardless of whether the event was related to the ICD system. A complication was defined as a clinical event that resulted in additional invasive intervention, injury, or death. An observation was defined as a clinical event that did not result in additional invasive intervention, injury, or death.

Table 1: Reported Adverse Events

Category	Number of Patients	Percentage of Patients	Number of AEs	AEs per patient-year
Overall Complications - Totals	**23**	**17.2%**	**23**	**0.31**
Lead-Related	**13***	**9.7%**	**13***	**0.17**
Atrial Lead Repositioning	10	7.5%	10	0.13
Ventricular Lead Repositioning	4	3.0%	4	0.05
Non-Lead Related	**10**	**7.5%**	**10**	**0.13**
Medical	5	3.7%	5	0.07
Device-Related	3	2.2%	3	0.04
Elevated DFT's	2	1.5%	2	0.03
Overall Observations – Total	**74**	**55.2%**	**135**	**1.81**
Atrial induction shock induced VT/VF	9	6.7%	10	0.13
Detection	9	6.7%	9	0.12
Elevated DFT's	3	2.2%	3	0.04
Far-field oversensing	12	9.0%	12	0.16
Inappropriate episode termination	12	9.0%	14	0.19
Ineffective atrial therapy	4	3.0%	4	0.05
Manual atrial shock not synchronous with ventricular event	3	2.2%	3	0.04
Medical	27	20.1%	30	0.40
Patient in AT/AF	8	6.0%	8	0.11
Phantom shock	4	3.0%	4	0.05
Programmer software I-HAT.0.U/3	5	3.7%	5	0.07
Programmer software I-HAT.0.U/4	3	2.2%	3	0.04
Sensing and pacing	19	14.2%	20	0.27
T-wave oversensing	8	6.0%	8	0.11
Other	2	1.5%	2	0.03

Number of Patients = 134, Number of Patient-Years = 74.7

*One patient underwent both an atrial and ventricular lead repositioning in the same procedure

Survival

There were 9 patient deaths reported. None of these deaths were related to the implanted ICD system. A summary of the deaths grouped into predefined categories is provided in **Table 2**.

Table 2: Patient Deaths - Summary

Category	Number of Patients	Percentage of Patients (n=134)
Sudden Cardiac	1	0.7%
Non-Sudden Cardiac	6	4.5%
Non-Cardiac	2	1.5%
Unexplained	0	0.0%
All Causes	**9**	**6.7%**

1.6 Summary of Clinical Study

Study Overview

The purpose of this study was to demonstrate the ability of the Tachos DR - Atrial Tx to detect and convert atrial tachyarrhythmias in patients that require standard ICD therapy and that have a history or significant risk of atrial tachyarrhythmias. The ICD is not intended for use in patients with only atrial tachyarrhythmias. All patients were implanted with the Tachos DR - Atrial Tx and then had both atrial and ventricular detection and therapy features enabled. All patients received standard anti-arrhythmic drug therapy as deemed appropriate by the investigator. The patients were followed at 1 month, 3 months and 6 months post-implant thereafter.

Induction and conversion of induced atrial and ventricular tachyarrhythmias was required after enrollment (or implant of the device). Stored data that documents the detection and conversion of spontaneous and induced atrial tachyarrhythmia episodes was retrieved from the implanted device. The atrial therapy features were enabled throughout the duration of the study.

Methods

The Tachos DR - Atrial Tx ICD was evaluated during the Tachos Atrial Conversion Therapy (TACT) Clinical Investigation. The TACT study was a multi-center, non-randomized clinical investigation conducted at 15 U.S. centers. The study had two predefined primary and five secondary endpoints.

The endpoints are listed below:

- Primary Endpoint 1: AT/AF Detection Sensitivity (Effectiveness)
- Primary Endpoint 2: Complication-Free Survival Rate (Safety) at 6 months
- Secondary Endpoint 1: Overall AT/AF Conversion Rate
- Secondary Endpoint 2: Atrial Shock Therapy Conversion Rate
- Secondary Endpoint 3: Atrial Burst Therapy Conversion Rate
- Secondary Endpoint 4: Atrial ATP Therapy Conversion Rate
- Secondary Endpoint 5: Quality of Life

This study was designed to demonstrate the effectiveness of the Tachos DR Atrial Tx to detect and convert atrial tachyarrhythmias in patients that require standard ICD therapy and that have a history or significant risk of atrial tachyarrhythmias. The safety of the device was tested through analysis of the complication-free survival rate. Additionally, the change in the quality of life (QOL) of the patient was evaluated by comparing a symptom checklist for baseline obtained at the time of enrollment and the one obtained at the three-month follow-up. A validated, symptom specific instrument for cardiac arrhythmias (Symptom Checklist – Frequency and Severity Scale[1]) was used to collect this supporting data.

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[1] Bubien, R. Effect of Radiofrequency Catheter Ablation on Health-Related Quality of Life and Activities of Daily Living in Patients with Recurrent Arrhythmias, Circulation 1996, Vol. 94, No. 7, 1585-1591.

Patient Selection Criteria

Inclusion criteria:

- Standard ICD indication
- History or significant risk of atrial tachyarrhythmias

Exclusion criteria:

- Have a life expectancy of less than six months
- Expected to receive heart transplantation within six months
- Enrolled in another cardiovascular clinical investigation
- Require a separate bradycardia pacemaker
- Atrial tachyarrhythmia refractory to cardioversion shock therapy

Patient Population Studied

BIOTRONIK began the TACT clinical investigation with the first US implant on December 21, 2000. As of February 1, 2002, 119 patients were being actively followed in the clinical study. **Figure 1** provides a patient accountability flowchart for the 134 patients enrolled into the TACT clinical investigation.

Figure 1: Patient Accountability Flowchart

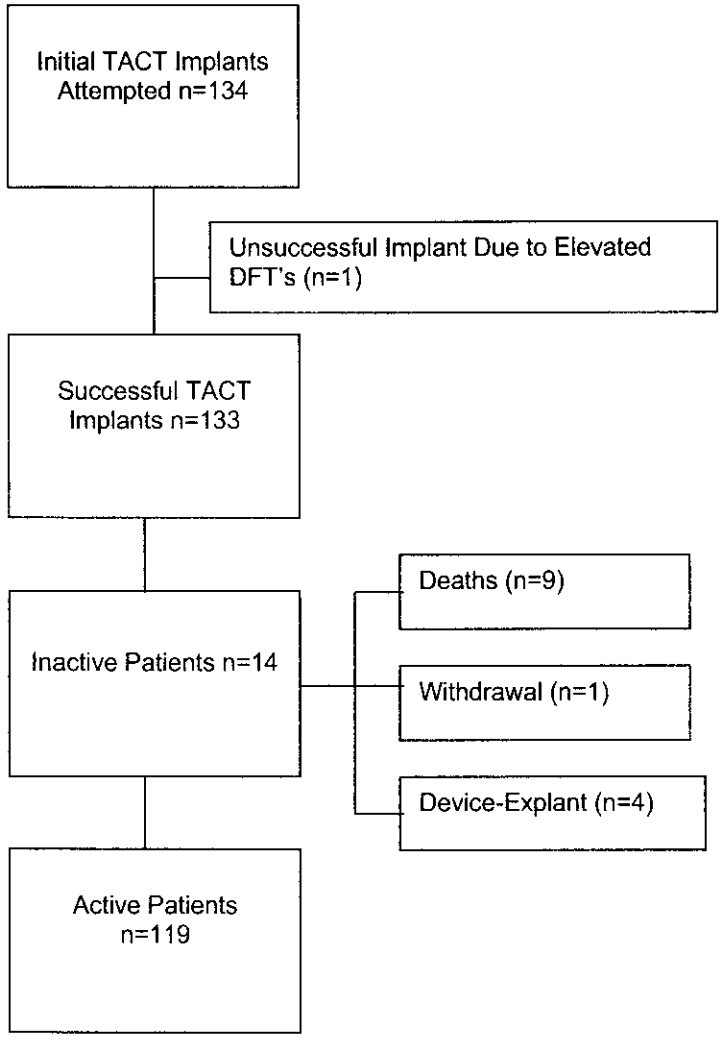


Table 3 provides a summary of the demographics of the patients enrolled in the TACT clinical study. Note that the percentage in some categories may total more than one hundred because several categories allow more than one response. In some cases, complete demographic data was not provided for all patients.

Table 3: Patient Characteristics

Characteristic	Results
Age at Implant (Years)	
Mean ± SE	68 ± 0.9
Range	46 to 86
Gender	
Male	107 (79.9%)
Female	27 (20.1%)
New York Heart Association Class	
Class I	14 (10.4%)
Class II	71 (53.0%)
Class III	45 (33.6%)
Class IV	2 (1.5%)
Unclassified	2 (1.5%)
Left Ventricular Ejection Fraction (%)	
Mean ± SE	31 ± 1.2
Range	5 to 70
Primary Cardiac Disease	
CAD / Ischemic Cardiomyopathy	99 (73.9%)
Nonischemic or Dilated Cardiomyopathy	21(15.7%)
Valvular Disease	6 (4.5%)
Primary Electrical Disease	5 (3.7%)
Other Cardiac Disease	3 (2.2%)
Primary Ventricular Tachyarrhythmias	
MVT	95 (70.9%)
VF/PVT	45 (33.6%)
Atrial Tachyarrhythmia Risk Factors	
Documented History	96 (71.6%)
Significant History	38 (28.4%)

Results

The cumulative implant duration is 896.3 months with average implant duration of 6.7 ± 0.3 months. A total of 110 patients had an implant duration of greater than 90 days during the study period of December 21, 2000 (the first implant of the Tachos DR-Atrial Tx) through February 1, 2002.

1.6.1 Follow-up Compliance

The follow-up compliance rate is equal to the total number of completed follow-ups divided by the total number of required follow-ups (missed and completed). There were 551 completed follow-ups out of a total of 561 required follow-ups. Therefore, the overall follow-up compliance rate is 98.2%. Table 4 outlines the follow-up compliance for all required follow-up intervals specified by the protocol.

Table 4: Follow-up Compliance Summary

Required Follow-up Interval	Follow-up Compliance # Compliant/Total Required (%)
Implant	143/143 (100.0%)
Pre-Discharge Follow-up	130/131 (99.2%)
One-Month Follow-up	111/117 (94.9%)
Three-Month Follow-up	102/102 (100.0%)
Routine Follow-up (every 6 months post-implant)	67/68 (98.5%)
All Required Follow-ups	**551/561 (98.2%)**

Primary Endpoint 1: AT/AF Detection Sensitivity (Effectiveness)

The purpose of primary endpoint 1 is to evaluate the AT/AF detection sensitivity, which is the ability of the atrial detection algorithm to appropriately detect AT (atrial tachycardia) and AF (atrial fibrillation). This endpoint was evaluated based on the review of stored electrograms following induction of AT/AF during supervised testing performed at implant and subsequent follow-ups. Of the 133 patients available for AT/AF induction testing, 14 were non-inducible or had non-sustained AT/AF, 2 were unstable and did not undergo AT/AF induction testing, and 2 were in refractory AT/AF. In addition, 1 had missing implant IEGMs data (source documentation). Therefore, data from 114 patients were available for evaluation of the primary endpoint.

Table 5 provides a summary of the results based on evaluations completed in the 114 patients. Some patients may have more than one type of atrial arrhythmia induced. Therefore the total number of patients will be less than the number of patients with each arrhythmia type.

Table 5: AT/AF Detection Sensitivity

Initial Arrhythmia	Patients	Episodes	Appropriate Detection
AT/AFI	40	80	77 (96.3%)
AF	95	211	206 (97.6%)
All Atrial Arrhythmias	**114**	**291**	**283 (97.3%)**

Primary Endpoint 2: Complication-Free Survival Rate (Safety)

The purpose of primary endpoint 2 is to evaluate the safety of atrial therapy. This endpoint includes all complications, which are adverse events that require additional invasive intervention to resolve. The estimate of complication-free survival at six months is based on a Kaplan-Meier actuarial analysis.

There were a total of 23 complications in 23 patients during the TACT clinical study. A summary of the complications is provided in **Table 6** below. One patient had both an atrial and a ventricular lead repositioning during one procedure, which is counted as one complication. Therefore the number of patients and events in each category of the Lead-Related complications are not equal to the actual Lead-Related total number of patients and complications.

Table 6: Complication Summary

Category	Number of Patients	Percentage of Patients	Number of Complications	Complication per patient-year
Lead-Related				
Atrial Lead Repositioning	10	7.5%	10	0.13
Ventricular Lead Repositioning	4	3.0%	4	0.05
Non-Lead Related				
Medical	5	3.7%	5	0.07
Device-Related	3	2.2%	3	0.04
Elevated DFT's	2	1.5%	2	0.03
Total Lead-Related	**13**	**9.7%**	**13**	**0.17**
Total Non-Lead Related	**10**	**7.5%**	**10**	**0.13**
Overall Complication Totals	**23**	**17.2%**	**23**	**0.31**

Number of Patients = 134, Number of Patient-Years = 74.7

The Kaplan-Meier complication-free survival estimates for typical implant durations are shown in **Table 7**. The Kaplan-Meier complication-free survival graph is shown in **Figure 2**.

Table 7: Complication-Free Survival - Kaplan-Meier

Implant Duration (Months)	Number Patients	Cumulative Survival (S)	Standard Error (SE)*	95% Confidence Interval**
3	100	87.4%	3.1%	(81.3%, 93.5%)
6	73	84.4%	3.9%	(76.8%, 92.0%)
9	37	78.0%	6.0%	(66.2%, 89.8%)
12	7	78.0%	13.8%	(51.0%, 100.0%)

Number of Patients = 134, Number of Patient-Years = 74.7
* Peto et al adjusted, ** S ± 1.96 SE

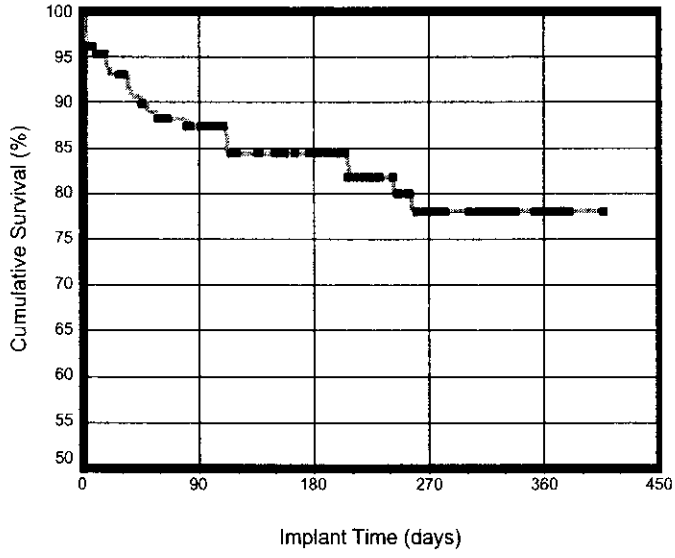


Figure 2: Complication-Free Survival – Kaplan-Meier Graph

The lower bound of the two-sided 95% confidence interval at six months (76.8%) is below the stated equivalence limit of 88% (95% - δ, where δ = 7%), as is the lower bound of the one-sided 95% confidence interval (78.0%). The null hypothesis is not rejected, and it is concluded that the complication-free rate is not equivalent to 95% within 7%. However, there were no reported complications related to atrial therapy, which supports the safety of the atrial detection and therapy features of the ICD. Furthermore, there were no study patients that experienced either a CVA (cerebrovascular accident) or stroke during this study. However, out of the 134 enrolled patients, 13 patients (9.7%) had lead-related complications and 10 (7.5%) had non-lead related types of complications. Again, none of these complications were related to the atrial detection or therapy features that are being evaluated as the focus of this clinical investigation.

Secondary Endpoints

The clinical study had five pre-defined secondary endpoints, which provided other pertinent information on the Tachos DR – Atrial Tx ICD performance. These secondary endpoints are listed below and the results from spontaneous episodes that occurred over the implant duration (up to 14 months) are combined in **Table 8** and **Table 9**.

1. Overall AT/AF Conversion Rate

The purpose of secondary endpoint 1 is to evaluate the overall ability of the device to appropriately convert AT (atrial tachycardia) and AF (atrial fibrillation).

2. Shock Therapy Conversion Rate

The purpose of secondary endpoint 2 is to evaluate the ability of shock therapy to convert atrial tachycardia and atrial fibrillation (AT/AF).

3. Atrial HF Burst Therapy Conversion Rate

The purpose of secondary endpoint 3 is to evaluate the ability of atrial high frequency (HF) burst therapy to convert atrial tachycardia and atrial fibrillation (AT/AF).

4. Atrial ATP Therapy Conversion Rate

The purpose of secondary endpoint 4 is to evaluate the ability of atrial ATP therapy to convert atrial tachycardia (AT).

5. Quality of Life

The purpose of secondary endpoint 5 is to evaluate any change in the quality of life (QOL) of the patient from baseline at the time of enrollment and the three-month follow-up. A validated, symptom specific instrument for cardiac arrhythmias (Symptom Checklist – Frequency and Severity Scale[1]) will be used to collect this supporting data. This instrument is formatted in the form of two symptom checklists and quantifies both symptom frequency and severity. The format allows respondents to use check marks to indicate both the frequency with which they have experienced each symptom and the severity for each symptom listed. Since the Symptom Checklist quantifies two aspects of symptom assessment: two independent scores are produced.

Table 8 includes the success of the therapy sequences for spontaneous episodes and **Table 9** includes the total number of spontaneous episodes and subsequent success of each atrial therapy and the quality of life data.

[1] Bubien, R. Effect of Radiofrequency Catheter Ablation on Health-Related Quality of Life and Activities of Daily Living in Patients with Recurrent Arrhythmias, Circulation 1996, Vol. 94, No. 7, 1585-1591.

Table 8: Atrial Therapy Sequences Success Detail

#	Therapy Sequences	Patients	Episodes	Successes	Success Rate
1	ATP	14	57	35	61.4 %
2	ATP, HF Burst	8	14	5	35.7 %
3	ATP, HF Burst, Shock	4	6	5	83.3 %
4	ATP, Shock	3	3	2	66.7 %
5	HF Burst	24	214	105	49.1 %
6	HF Burst, Shock	14	26	22	84.6 %
7	Shock	15	27	18	66.7 %
All Therapy Sequences		43	347	192	55.3 %

Table 9: Secondary Endpoint Results

Secondary Endpoint Description	**Result** [95% CI]
1. Overall AT/AF Conversion Rate	55.3% (192 out of 347 episodes) [49.9%, 60.6%]
2. Shock Therapy Conversion Rate	74.1% (46 out of 62 episodes) [61.5%, 84.5%]
3. Atrial HF Burst Therapy Conversion Rate	42.3% (110 out of 260 episodes) [36.2%, 48.6%]
4. Atrial ATP Therapy Conversion Rate	45.0% (36 out of 80 episodes) [33.8%, 56.5%]
5. Quality of Life • Improvement in average frequency • Improvement in average severity	 6.9 ($p < 0.001$) 5.7 ($p < 0.001$)

Additional Results

The TACT clinical study allowed the use of all commercially available atrial leads. However, a BIOTRONIK dual-coil ICD lead was required. **Table 10** and **Table 11** provide a summary of the various lead types used during the course of the study. Note that the tables include only leads that are from the initial implanted system.

Table 10: Atrial Leads

Manufacturer & Lead Model	Number and Percentage of All Implanted Leads
Biotronik	
Elox	73 (54.8%)
Retrox	20 (14.9%)
Synox	11 (8.2%)
Polyrox	8 (6.0%)
Guidant	
Fineline	2 (1.5%)
Fineline EZ	1 (0.7%)
Medtronic	
CapSureFix	7 (5.2%)
CapSureFix Novus	2 (1.5%)
CapSureZ Novus	2 (1.5%)
Oscor Medical	
Oscor	1 (0.7%)
St. Jude	
Tendril SDX	5 (3.7%)
Tendril	1 (0.7%)
Tendril DX	1 (0.7%)
All Models	**134 (100%)**

Table 11: ICD Leads

Manufacturer & Lead Model	Number and Percentage of All Implanted Leads
Biotronik	
Kainox SL	132 (98.5%)
SL-ICD	1 (0.75%)
Medtronic	
Sprint	1 (0.75%)
All Models	**134 (100%)**

The one patient implanted with a Medtronic ICD lead (**Table 11**) required an active-fixation dual-coil ICD lead due to patient's anatomy and multiple unsuccessful attempts at re-positioning the ventricular lead during the implant procedure.

Table 12 represents the lead measurement data obtained during the implant procedure, 3 month follow-up interval, and other follow-ups which generally occurred beyond the 3 month follow-up interval.

Table 12: Lead Measurements

Lead Measurement	Implant	3-Month Follow-up	Other Follow-ups
P-Wave (millivolts)			
Number of Tests	142	97	239
Mean ± SE	3.2 ± 0.1	3.4 ± 0.2	3.0 ± 0.1
Range	0.8 to 6.3	0.4 to 6.3	0.4 to 6.3
Atrial Pacing Threshold @ 0.5 ms (Volts)			
Number of Tests	134	92	205
Mean ± SE	0.8 ± 0.1	1.2 ± 0.1	1.2 ± 0.1
Range	0.2 to 5.8	0.2 to 5.8	0.1 to 6.6
Atrial Pacing Impedance (Ohms)			
Number of Tests	141	101	244
Mean ± SE	453 ± 10.0	473 ± 17.0	477 ± 11.7
Range	330 to 950	320 to 1210	280 to 1250
R-Wave (millivolts)			
Number of Tests	142	99	249
Mean ± SE	12.2 ± 0.1	12.9 ± 0.4	12.0 ± 0.2
Range	2.8 to 16.0	3.0 to 16.0	2.1 to 16.0
Ventricular Pacing Threshold @ 0.5 ms (Volts)			
Number of Tests	138	101	224
Mean ± SE	0.6 ± 0.0	1.2 ± 0.1	1.2 ± 0.1
Range	0.2 to 1.7	0.4 to 6.8	0.3 to 7.2
Ventricular Pacing Impedance (Ohms)			
Number of Tests	142	101	244
Mean ± SE	589 ± 10.0	582 ± 10.8	551 ± 7.0
Range	410 to 920	280 to 870	270 to 970

Ventricular Tachyarrhythmias

The ICD is designed to provide ventricular tachyarrhythmia therapy in addition to atrial tachyarrhythmia therapy. All patients are required to have standard ventricular ICD indications prior to enrollment. Information about the episodes of VT/VF was also collected during the study as additional data of interest. **Table 13** provides a summary of the spontaneous ventricular

tachyarrhythmias detected and resulting in appropriate ventricular therapy during the study. Note that some patients may have had more than one arrhythmia type, therefore the total number of patients will be less than the number of patients with each arrhythmia type.

Table 13: Spontaneous VT/VF Episodes

Detection Zone	Number of Patients	Number of Episodes	Successful Conversions	% Success
VT-1/VT-2	11	152	152	100%
VF	10	30	30	100%
Totals	17	182	182	100%

Atrial Tachyarrhythmia Conversion Testing

Atrial conversion testing was performed to assess the atrial DFT shock energy. The protocol required two atrial conversions of AT/AF. This was accomplished by atrial inductions followed by delivery of either device initiated cardioversion shocks or manual shocks delivered through the device. The investigators were instructed to wait a minimum of one minute after AT/AF induction prior to assessing the atrial DFT. If the first cardioversion shock was unsuccessful, a higher energy shock was delivered until cardioversion was achieved or until the maximum cardioversion energy was reached. Investigators employed varied testing methods including: true step-up testing, step-down testing, inducing and converting dual arrhythmias simultaneously or simply completing two atrial conversions at an energy that would provide an adequate conversion safety margin. Therefore the data presented in the following table may not accurately reflect the true atrial DFT.

Table 14 provides a summary of the atrial DFT results during implantation and separate results for follow-up testing. Atrial DFT testing was only required by the protocol during the implant procedure. However, the investigators were encouraged to induce atrial tachyarrhythmias at subsequent follow-ups. Some patients may have more than one type of atrial arrhythmia induced. Therefore the total number of patients will be less than

the number of patients with each arrhythmia type. 115 patients of 134 had inducible atrial tachyarrhythmias at implant.

Table 14: Atrial Defibrillation Thresholds

Type of Tests	Results at Implant (Joules)	Results at Follow-Ups (Joules)
Lowest Converting Energy (AF)		
Number of Patients	91	17
Mean ± SE	6.1 ± 0.6	11.8 ± 0.8
Range	1 to 30	3 to 30
Lowest Converting Energy (AT/AFI)		
Number of Patients	30	4
Mean ± SE	5.2 ± 0.9	4.8 ± 0.5
Range	1 to 20	2 to 10

Inappropriate Atrial Episodes

During the TACT study, 1021 atrial episodes have been detected in the AT/AF zones. However, in some cases episodes were inappropriately detected as atrial tachyarrhythmia episodes. Inappropriate atrial episodes are defined as atrial episodes detected by the device when the patient was not in an atrial arrhythmia. Far-field oversensing of the ventricular channel due to sub-optimal programming of atrial detection parameters or an atrial lead dislodgement were the primary causes of inappropriate atrial detection. As a result, inappropriate atrial detection was usually resolved by either reprogramming the ICD by extending the Ablank_Vsense and/or Ablank_Vpace parameters, decreasing the atrial sensitivity, or by performing an atrial lead revision.

Table 15 summarizes the incidence of spontaneous inappropriate atrial episodes. Both the numbers of patients and episodes are not mutually exclusive since some patients had more than one type of therapy delivered and some episodes had more than one type of therapy delivered.

Table 15: Inappropriately Detected Atrial Episodes

Inappropriate Episode Category	Number (%) of Total Patients n = 134	Number (%) of All Episodes n = 1021
No Atrial Therapy Delivered	13 (9.7%)	38 (3.7%)
Inappropriate Atrial Therapy Delivered:	11 (8.2%)	133 (13.0%)
Atrial ATP	7* (5.2%)	66* (6.5%)
HF Burst	5* (3.7%)	67* (6.6%)
Atrial Shock	2* (1.5%)	3* (0.3%)
Total/causes of Inappropriate Detection:	19 (14.2%)	171 (16.7%)
Far-field Oversensing of the Ventricular Channel	19* (14.2%)	170 (16.7%)
Paced Ventricular Atrial Refractory Period Programming	1* (0.7%)	1 (0.1%)

***Not mutually exclusive. Patients or episodes may have included more than one type of inappropriate atrial detection or inappropriate therapy.**

Multi-site Poolability and Gender Analysis

The clinical report includes data from multiple centers with centralized coordination, data processing, and reporting at BIOTRONIK. All of the clinical centers followed the requirements of an identical clinical protocol, and all of the clinical centers used the same methods to collect and report the clinical data. In order to justify pooling of the data from multiple centers, several analyses were completed. All of the centers were divided into two groups based on implant volume. Comparisons were then made between the patient populations based on the results of each of the endpoints. Additionally, analyses were performed on the data collected in the IDE clinical investigation in order to compare results between males and females. The first type of analysis compared enrollment by patient gender to other clinical studies. The second type of analysis compared the safety and efficacy in each gender.

The results of these analyses demonstrate poolability of the data between sites. There were no significant differences in the second primary endpoint or any of the secondary endpoints between high and low volume implant centers. There was a significant difference in the adjusted atrial detection rate between patients enrolled at low volume sites and those at high volume sites. However, the atrial detection rates in both groups exceeded the 87% target rate.

The gender distribution in this clinical investigation is consistent with other clinical studies and includes a representative proportion of female participants. There were no significant differences in any of the primary or secondary endpoints between the male and female population.

1.6.2 Atrial Detection and Therapy Programming

Please refer to **Appendix B** for atrial detection and therapy programming recommendations. This section is intended to provide general programming recommendations for atrial detection and therapy, based on the experience with the device during the clinical study. During the study, BIOTRONIK collected information about the programming of specific atrial detection and therapy parameters.

1.6.2.1 Atrial Detection

The average device was programmed with 2 atrial tachyarrhythmia zones (AF and AT-1) with an average rate cut-off of 263 ms for the AF zone and 338 ms for the AT-1 zone. Atrial zone programming should be customized to every patient.

1.6.2.2 Atrial Therapy

During the clinical study it was found that the atrial HF burst therapy had a success rate of 42.3%. Therefore BIOTRONIK recommends using HF burst as the first therapy in the AF zone. Multiple bursts should be programmed in order to optimize the chance of converting the atrial tachyarrhythmia with this painless therapy.

PRECAUTION

Straight Atrial Leads - When using a straight atrial lead e.g. non-preformed "J", a 1-month waiting period is recommended prior to programming atrial HF Burst therapy. This important consideration is related to the increased likelihood of atrial lead dislodgement during the first month after implant. A dislodged straight atrial lead could potentially fall in the ventricle and could subsequently result in the delivery of an undesired ventricular HF burst.

Atrial shock programming is recommended as progressive therapy in the AT and AF zone. The clinical study results demonstrated an atrial shock conversion success rate of 74.1%. Shock energy programming should be optimized based on atrial DFT testing to ensure a sufficient safety margin. When programming shock energies, one should consider that a patient is more likely to receive multiple shocks due to unsuccessful conversion from ineffective low energy shocks, rather than a single high-energy shock. Additionally, previous studies have shown that the patient discomfort experienced for a 1 joule, shock is similar to that of higher energy shocks (Lok, N. et al; PACE 1996 Volume 19, P. 633).

ATP therapy showed to have a success rate of 45.0% for conversion of atrial tachycardia. Therefore, it is suggested to use ATP therapy as the first therapy in each programmed AT zone. Multiple attempts should be programmed to increase the likelihood of success.

Because atrial tachyarrhythmias are not immediately life threatening, atrial therapy can be delayed to allow for potential spontaneous termination of the tachyarrhythmia. Two programmable delays are available to accomplish this: AT-1 therapy delay and atrial shock delay. Refer to sections **2.4.3** and **2.4.7** for explanation of these delay features.

Please refer to **Appendix B** for atrial detection and therapy programming recommendations.

1.7 Patient Selection and Treatment

1.7.1 Individualization of Treatment

- Determine whether the expected device benefits outweigh the possibility of early device replacement for patients whose ventricular tachyarrhythmias require frequent shocks.
- Direct any questions regarding individualization of patient therapy to your BIOTRONIK representative or BIOTRONIK technical services at 1-800-547-0394.

The prospective patient's size and activity level should be evaluated to determine whether a pectoral or abdominal implant is suitable. It is strongly recommended that candidates for an ICD have a complete cardiac evaluation including EP testing prior to device implant to gather electrophysiologic information, including the rates and classifications of all the patient's cardiac rhythms. When gathering this information, delineate all clinically significant ventricular and atrial arrhythmias, whether they occur spontaneously or during EP testing.

If the patient's condition permits, use exercise stress testing to do the following:

- Determine the maximum rate of the patient's normal rhythm.
- Identify any supraventricular tachyarrhythmias.
- Identify exercise-induced tachyarrhythmias.

The maximum exercise rate or the presence of supraventricular tachyarrhythmias may influence selection of programmable parameters. Holter monitoring or other extended ECG monitoring also may be helpful.

If the patient is being treated with antiarrhythmic or cardiac drugs, the patient should be on a maintenance drug dose rather than a loading dose at the time of pulse generator implantation. If changes to drug therapy are made, repeated arrhythmia inductions are recommended to verify pulse generator detection and conversion. The pulse generator also may need to be reprogrammed.

Changes in a patient's antiarrhythmic drug or any other medication that affect the patient's normal cardiac rate or conduction can affect the rate of tachyarrhythmias and/or efficacy of therapy.

If another cardiac surgical procedure is performed prior to implanting the pulse generator, it may be preferable to implant the lead system at that time. This may prevent the need for an additional thoracic operation.

1.7.2 Specific Patient Populations

Pregnancy - If there is a need to image the device, care should be taken to minimize radiation exposure to the fetus and the mother.

Nursing Mothers - Although appropriate biocompatibility testing has been conducted for this implant device, there has been no quantitative assessment of the presence of leachables in breast milk.

Handicapped and Disabled Patients - Special care is needed in using this device for patients using electrical wheel chair or other electrical (external or implanted devices).

1.8 Patient Counseling Information

- The pulse generator is subject to random component failure. Such failure could cause inappropriate shocks, induction of arrhythmias or inability to sense arrhythmias, and could lead to the patient's death.
- Persons administering CPR may experience the presence of voltage on the patient's body surface (tingling) when the patient's ICD system delivers a shock.

A patient manual is available for the patient, patient's relatives, and other interested people. Discuss the information in the manual with concerned individuals both before and after pulse generator implantation so they are fully familiar with operation of the device. (For additional copies of the patient manual, contact the BIOTRONIK at the address listed in this manual.)

1.9 Evaluating Prospective ICD Patients

The prospective ICD implant candidate should undergo a cardiac evaluation to classify any and all tachyarrhythmias. In addition, other patient specific cardiac information will help in selecting the optimal device settings. This evaluation may include, but is not limited to:

- an evaluation of the specific tachycardia rate(s)
- the confirmation and/or evaluation of any supraventricular arrhythmias or bradyarrhythmias
- the evaluation of various ATP and cardioversion therapies
- the presence of any post-shock arrhythmias, and
- an evaluation of the maximum sinus rate during exercise

If a patient's drug regimen is changed or adjusted while the ICD is implanted, additional EP testing may be required to determine if detection or therapy parameter settings are relevant and appropriate.

Empirical changes to the detection or therapy parameters should be assessed based on patient safety. Some changes may necessitate a re-assessment of sensing, pacing, or arrhythmia conversion treatment. Thorough technical knowledge of BIOTRONIK ICDs, additional ICD experience, and individual medical judgment will aid in determining the need for additional testing and follow-up.

2. Device Features

The Tachos DR - Atrial Tx feature set is presented under the following sub-headings: Sensing, Tachyarrhythmia Detection, Tachyarrhythmia Redetection / Acceleration, Tachyarrhythmia Therapy, Bradycardia Therapy, EP Test Functions and Special Features.

2.1 Sensing

The Tachos DR - Atrial Tx uses Automatic Sensitivity Control (ASC) and Automatic Gain Control (AGC) to adjust the input stage sensitivity threshold and gain characteristics to appropriately detect the various cardiac signals. The characteristics of the sensing circuitry have been optimized to ensure appropriate sensing during all of a patient's cardiac rhythms.

Cardiac signals vary in amplitude, therefore, detection thresholds cannot be static. The Automatic Sensitivity Control (ASC) in Tachos DR - Atrial Tx utilizes an automatic step-down threshold in the atrium and ventricle. The ASC begins by tracking the cardiac signals (i.e. P-wave in the atrium and R-wave in the ventricle) during the sensed refractory periods. The peak values measured during this time are used to set the thresholds. The upper threshold is set at 50% of the R-wave (or P-wave). The upper threshold remains active from the sensed refractory period through the first threshold step (the next 125 ms in the ventricle or the next 82 ms in the atrium). After the first threshold step, the threshold is decreased to the lower threshold. The lower threshold is set to 25% of the measured peak or the maximum programmed sensitivity—whichever is greater.

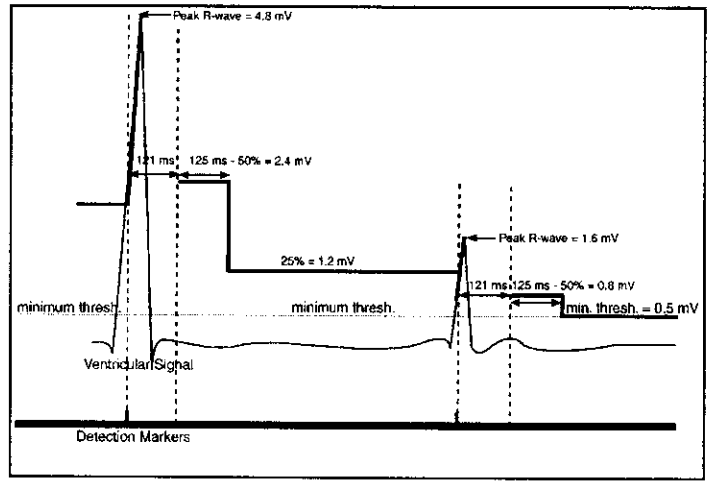


Figure 3. Sensitivity in the Ventricle

Figure 3 illustrates the ASC during ventricular sensing. The first R-wave is tracked and determined to be 4.8 mV at its peak. Following the sensed refractory period, the upper threshold is set 50% of the measured R-wave or 2.4 mV. After the threshold step duration, the threshold is reduced again to 25 % of the R-wave amplitude or 1.2 mV. The lower threshold is maintained until detection of the next R-wave. After the new R-wave is tracked, the upper threshold resets to 50% of the new R-wave amplitude (i.e. 0.8 mV). This threshold remains active throughout the threshold step. At this time, the threshold is set to 0.5 mV, as the minimum threshold (i.e. maximum sensitivity equal to 0.5 mV) is greater than 25% of the measured R-wave (i.e. 0.4 mV). ASC works similarly in the atrium as shown in Figure 4.

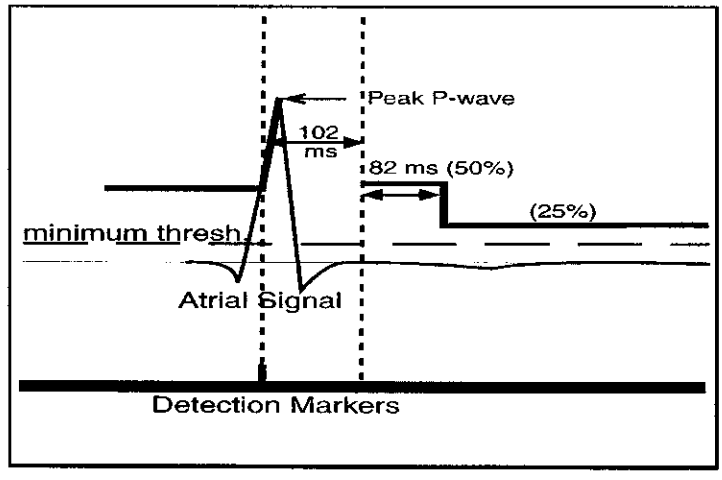


Figure 4. Sensitivity in the Atrium

The Tachos DR - Atrial Tx uses an automatic gain feature in the ventricle to adjust the sensitivity of the hardware to one of two different gain settings. The hardware automatically switches between the settings based on the amplitude of the sensed signal. When the R-wave amplitude is large, a low gain setting of ±16 mV is used. When the R-wave amplitude is small, the high gain setting of ±4 mV is used. In each gain setting the range is divided into 32 equal steps, therefore, the resolution equals 0.5 mV in low gain and 0.125 mV in high gain.

After a paced event, the gain is automatically set to high in the ventricle. This ensures that the sensing threshold will be defined with high resolution between the minimum threshold and 2 mV (i.e. 50% of the maximum amplitude of 4 mV seen in high gain). This setting minimizes the potential of pacing in the presence of ventricular fibrillation.

As with sensed events, the upper and lower thresholds are reset after a paced event following the refractory period. Unlike ASC during sensing, the threshold may decrease below the lower threshold after paced events (i.e. more than one threshold step is allowed). However, the threshold will never fall below the maximum sensitivity.

2.1.1 T-Wave Suppression

There are three programmable options designed to alleviate the oversensing of T-waves as ventricular tachyarrhythmia signals. The default value for T-wave Suppression is Normal and most devices should remain programmed to this default value. BIOTRONIK recommends use of the extended T-wave parameter only in cases where large T-waves are detected by the device resulting in "double counting."

NOTE:

Should double counting occur after paced events, lengthen the paced refractory period to eliminate oversensing.

T-wave Suppression is also programmable to Large T, Long QT or Large T + Long QT. When programmed to Large T, the threshold step window is set to 75% of the measured R-wave (1st hold off) to avoid sensing large T-waves. When programmed to Long QT, the threshold step duration automatically lengthens (2nd hold off) to avoid sensing large T-waves.

Figure 5 provides a pictorial representation of the T-wave Suppression parameters. When programmed to Large T + Long QT, the threshold step duration and level are automatically lengthened and increased (both 1st and 2nd hold off) to avoid sensing large, wide T-waves.

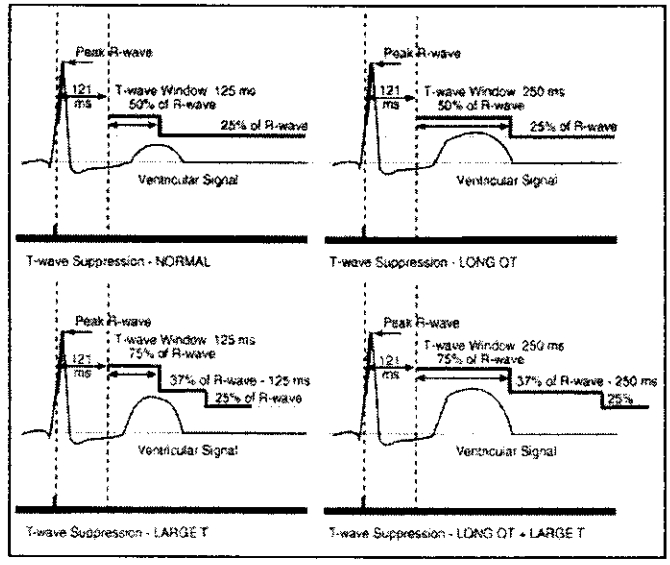


Figure 5. T-wave Suppression

The T-wave suppression parameters should be used whenever the ICD's filters are unable to reduce the T-wave amplitude to undetectable levels.

NOTE:

If the "Large T" or "Long QT & Large T" options are selected. A message appears that states: "The algorithms for prevention of T-wave oversensing lead to higher energy consumption. This shortens the service time of the device."

2.1.2 Maximum Atrial Sensitivity

This parameter limits the maximum sensitivity of the atrial channel. It may be modified in the event that atrial oversensing is observed.

2.1.3 Maximum Ventricular Sensitivity

This parameter limits the maximum sensitivity of the ventricular channel. It may be modified in the event that ventricular oversensing is observed.

2.1.4 Paced Refractory Periods

The refractory periods after paced events are separately programmable for the atrium and the ventricle.

2.1.5 Additional Sensing Parameters

Because accurate sensing is essential for appropriate rhythm classification, Tachos DR - Atrial Tx includes detailed parameters to modify the sensing settings of the ICD. A BLANK-V PACE, A BLANK-V SENSE, RAISE ATR THRESHOLD, and EARLY FAR-FIELD TOLERANCE can correct inappropriate sensing of ventricular far-fields signals in the atrium.

PRECAUTION

Far-field sensing of signals from the atrium in the ventricular channel or ventricular signals in the atrial channel should be avoided by appropriate lead placement, programming of pacing/sensing parameters, and maximum sensitivity settings. If it is necessary to lengthen A BLANK-V PACE or A BLANK-V SENSE, the parameter should be lengthened only long enough to eliminate far-field sensing as evidenced on the IEGMs. Extending either parameter unnecessarily may cause undersensing of actual atrial or ventricular events.

A BLANK-V PACE and A BLANK-V SENSE parameters initiate a short blanking period in the atrium with a ventricular event. The A BLANK-V PACE parameter initiates an atrial blanking period with each ventricular pace, while the A BLANK-V SENSE parameter initiates an atrial blanking period with each ventricular sense.

The RAISE ATR THRESHOLD parameter, when programmed in conjunction with A BLANK-V SENSE, increases the atrial detection threshold level above the nominal values. When the parameter is programmed to 2X, the atrial threshold is doubled after the programmed A BLANK-V SENSE (and A BLANK-V PACE) time. When the parameter is programmed to MAX, the atrial threshold is raised to twice the current value or to 2.0 mV whichever is greater.

EARLY FAR-FIELD TOLERANCE is used when far-field sensing results in a pseudo 2:1 rhythm. This scenario is most likely to occur when the ventricular signal is wide, creating far-field sensing before the ventricular event. In this case, if the AV interval is less than the programmed far-field tolerance (nominally 8 ms), then the rhythm is evaluated as a 1:1 signal (i.e. in terms of detection, the far-field event is ignored).

2.2 Tachyarrhythmia Detection

The ICD detects and measures the rate of sensed cardiac signals to discriminate ventricular tachyarrhythmias from sinus rhythm or sinus bradycardia. If a tachyarrhythmia is detected, the ICD classifies the arrhythmia and delivers the appropriate therapy. If a tachyarrhythmia persists following the first therapy attempt, then the ICD will re-detect the tachyarrhythmia and deliver subsequent therapies as programmed.

WARNING

Unwanted Shocks – Always program the therapy status to DISABLED prior to handling the device to prevent the delivery of serious shocks to the patient or the person handling the device during the implant procedure.

Classification of the cardiac rhythm is primarily accomplished by measuring the cardiac cycle lengths (R-R, P-R and P-P). In addition, the ICD can also utilize abrupt changes in rate, or irregularity of the cardiac signal to further differentiate tachyarrhythmias. Each detected tachyarrhythmia is classified into one of the following zones:

VT-1	Lower rate ventricular tachycardia
VT-2	Higher rate ventricular tachycardia
VF	Ventricular fibrillation
AT–1	Lower rate atrial tachycardia
AT–2	Higher rate atrial tachycardia
AF	Atrial fibrillation

Each rhythm class has a programmable rate range with the zone limit defining the lowest rate in each class. The upper rate limit of a class is equal to the zone limit of the next higher class, creating a continuous range of rate classes. The VF upper rate limit is determined by the non-programmable tachyarrhythmia ventricular detection refractory period. The AF upper rate limit is determined by similar criteria related to the atrial detection refractory periods.

NOTE:

A warning message reminds the user that Atrial detection with Atrial therapies disabled is intended for EP testing only, and to set atrial detection to OFF. This combination of atrial detection without atrial therapies could (under certain patient conditions) unnecessarily increase power consumption.

2.2.1 VF and AF Classifications

Detection of atrial and ventricular fibrillation (AF and VF) utilize separately programmable X out of Y criterion. Both X and Y are programmable within each arrhythmia class. If X number of intervals within the sliding window (defined by Y) are shorter than the programmed (AF or VF) rate interval (>bpm), AF or VF is detected. After fibrillation is detected, the programmed therapy sequence for the arrhythmia class (AF or VF) is initiated.

Nominal settings for classification of ventricular fibrillation (VF) are 8 of 12 intervals; meaning that within a sample window of 12 intervals, 8 intervals must meet or exceed the VF zone rate criteria. Atrial fibrillation detection is nominally programmed OFF.

2.2.2 VT and AT Sample Counts

The VT Sample Count applies to both the VT–1 and VT–2 rate classifications. Likewise, the AT–1 and AT–2 rate classifications are governed, by a separately programmable AT Sample Count. The Sample Count is the number of intervals required to declare a tachyarrhythmia as VT or AT. A tachyarrhythmia must meet both the Rate/Interval criteria and the programmed (VT or AT) Sample Count criteria, in addition to any other detection enhancements to be declared a tachycardia.

2.2.3 VT Classification

Both VT-1 and VT-2 classification zones in the Tachos DR - Atrial Tx utilize identical detection parameters. Classification of VT-1 or VT-2 is based on the last interval average preceding declaration of tachyarrhythmia detection. If this average falls within the VT-1, the programmed VT-1 therapy is delivered. If the average falls within the VT-2 limits, the programmed VT-2 therapy is delivered. If additional detection parameters are activated, each of these supplemental criteria must also be satisfied before a VT rhythm can be classified.

The Tachos DR - Atrial Tx may be programmed to use ventricular-only information, or both atrial and ventricular information for the discrimination of ventricular tachycardias. With SMART Detection™ turned ON, the Tachos DR - Atrial Tx uses atrial and ventricular signals for discrimination of fast heart rhythms. With SMART Detection™ turned OFF, only the ventricular rate is used to discriminate between ventricular rhythm classes. If SMART Detection™ is enabled, this algorithm evaluates all cardiac signals within the VT range and increments the VT Sample Count for all intervals deemed VT. A full description of SMART Detection™ is provided in the following text.

In addition, when the Tachos DR - Atrial Tx senses the programmed number of consecutive intervals (termination count) within the sinus rate zone, all tachyarrhythmia detection criteria, including the VT and AT sample counters are reset. AT and VT termination counts are separately programmable.

2.2.4 AT Classification

AT-1 and AT-2 classification zones in the Tachos DR - Atrial Tx utilize somewhat different detection parameters in classifying atrial arrhythmias. Classification of AT-1 and AT-2 are primarily based on the rate of the atrial rhythm. Separate counters for each zone utilize a sliding average of the four most recently measured atrial intervals.

If this average atrial interval falls within the AT-1 zone, the AT–1 counter is incremented. If the average falls within the AT-2 limits, the AT–2 counter is incremented. Additional detection parameters available for detection of atrial tachycardias in the AT-1 zone include Onset and various junctional criterion as described in the following sections, each of these supplemental criteria must also be satisfied before an AT-1rhythm is classified. AT–2 zone detection is based solely on the atrial interval measurements (rate).

2.2.5 SMART Detection™

This discrimination algorithm enhances VT-1 and VT-2 detection by applying a series of tests to the sensed cardiac signal. SMART Detection™ is intended to discriminate VT from a variety of supraventricular arrhythmias that are conducted to the ventricle and that would otherwise satisfy VT-1 or VT-2 rate detection criteria.

First, the average ventricular rate is compared to the average atrial rate. In the event that the measured ventricular rate is faster than the atrial rate, the device immediately declares the rhythm a VT and delivers programmed ventricular therapy for the detected VT zone.

In the event that an atrial rate is faster compared to the ventricular rate one of three tests are performed:

- Ventricular rhythm stability (see Stability on page 48), if the ventricular signal is unstable then the rhythm is declared a supraventricular tachyarrhythmia (SVT) and ventricular therapy is typically withheld.
- If the ventricular signal is stable, and the atrial rate is a multiple of the ventricle rate, then the rhythm is declared a supraventricular tachyarrhythmia (SVT) and ventricular therapy is typically withheld.
- If the ventricular rhythm is stable and the atrial rate is not a multiple of the ventricular rate, then the rhythm is declared a VT and ventricular tachycardia therapy is delivered.

In the event that both the atrial and ventricular signals are detected at the same rate, a series of additional discrimination tests are applied. The Smart Detection™ algorithm does not effect the detection and classification of atrial tachyarrhythmias.

SMART II is designed to improve AV discrimination for the patient with retrograde conduction through utilization of "active" discrimination. Active discrimination delivers pacing pulses in the ventricle and then evaluates the atrial response for retrograde conduction. SMART II enhances the SMART Detection™ algorithm, which must be enabled before SMART II can be programmed ON. The 1:1 Active Discrimination parameter located in the Advanced DETECTION screen activates SMART II. This 1:1 active discrimination algorithm replaces the sudden onset criteria in SMART Detection™ algorithm.

The 1:1 Active Discrimination parameter defines the number of intervals, required to initiate the active discrimination algorithm. This count is programmable and is incremented each time the atrial and ventricular rates are stable and equal. After the active discrimination count is met, the ICD delivers a single premature ventricular pacing pulse to check for retrograde conduction. The ICD determines that retrograde conduction exists if the programmed number of tests (Retrograde Confirmation at) indicate that retrograde conduction is present. The Number of Extra Stimuli parameter defines the maximum number of active discrimination tests that will be performed, unless retrograde conduction is confirmed prior to completing the programmed number of tests. The Tolerance for Antegrade parameter defines the maximum change in atrial interval length that can occur due to an extra stimulus and still be considered a change consistent with antegrade conduction (i.e. the maximum change for a negative retrograde test pulse).

Several other parameters determine the exact timing of the extra stimuli including; Initial Prematurity, Incremental Prematurity, Minimum R-S1 Interval. The Change Before Repeat parameter defines the acceptable amount that the V-V average for a 1:1 rhythm may change before the active discrimination test is re-initiated.

2.2.6 AT–1 Onset Delta / Sudden Onset Delta

Another detection enhancement that may be used independently in the following tachyarrhythmia zones: AT–1, VT–1 or VT–2, or as an adjunct to the SMART Detection™ algorithm, is the Onset Delta parameter. This parameter measures abrupt changes in ventricular cycle length to discriminate between sinus tachycardias and ventricular and atrial tachyarrhythmias, which characteristically begin with an abrupt change in cardiac rate.

This feature allows therapy to be withheld if a sinus tachycardia rate crosses into the AT–1 zone or one of the VT zones when activated.

2.2.7 Stability

In VT-1 and VT-2 zones, the purpose of STABILITY is to assist in discriminating between stable ventricular tachyarrhythmias and supraventricular tachyarrhythmias that conduct irregularly to the ventricles. STABILITY evaluates sudden changes in the regularity of cardiac events (R-R and P-P intervals) on a beat by beat basis. The STABILITY criterion compares the current measured interval with the three preceding cardiac intervals. If a difference between the current interval and each of the three preceding intervals is less than the stability range, then the current intervals are stable.

In the AT-2 zone, Stability is used to determine what therapy to provide based on the atrial arrhythmia (i.e., if the rate is unstable ATP therapy is skipped and programmed shock therapy is delivered). Stability is separately programmable for ventricular and atrial tachycardia zones.

The SMART Detection™ algorithm utilizes both atrial and ventricular STABILITY as integral parts of the discrimination algorithm. Therefore, when SMART Detection™ is enabled, the ventricular STABILITY parameter must also remain enabled and set to 12%.

2.2.8 Safety Timer

The Safety Timer can be programmed between 30 seconds and 30 minutes (or to OFF). When the safety timer expires, therapy is initiated regardless of the detection enhancements.

A simple up/down counter is used to initiate the safety timer. The counter is incremented by one when an interval falls into the VT zone and decrements by one when an interval falls into the sinus zone. When the counter reaches a number equal to the programmed VT sample count, the safety timer starts. The timer runs until the programmed time expires and therapy is delivered or until the timer is reset. The timer is reset by six consecutive intervals in the sinus zone.

The safety timer is not used in redetection. If initial detection was due to the safety timeout and SMART redetect after VT or VF is programmed "ON", then SMART Detection™ will not be used for redetection.

If SMART Detection is programmed "ON", the Safety Timer Mode can be programmed to act as a Total or Specific override timer as described as follows:

Total Safety Timer

When the Safety Timer Mode is programmed to total (the nominal value), the timer will override all cases of SVT/ST defined in SMART Detection™ (or stability and onset in ventricular-only detection). Therapy will be initiated for the SVT conditions as soon as the timer expires.

Specific Safety Timer

The Specific safety timer mode can only be programmed with SMART Detection™. The specific timer overrides one specific rhythm in which SMART Detection™ withholds therapy. This timer overrides a rhythm in which the atrial rate is faster than the ventricular rate and the ventricular rhythm is unstable. In this case, there is a small chance that the rhythm could be a polymorphic VT (i.e. because of the instability of the ventricular rhythm) with a concomitant atrial arrhythmia.

2.2.9 Junctional AV Limit and All Junctional

When AT–1 Onset is programmed to SINUS T, then atrial tachycardia (in the AT–1 zone) will only be classified if the ALL JUNCTIONAL parameter is turned ON and the JUNCTIONAL AV LIMIT criteria is met. When ALL JUNCTIONAL is programmed ON, the atrial detection scheme evaluates both the AV and VA intervals on a beat to beat basis. For an AV (or VA) interval to meet the junctional criterion, the current interval and each of the previous three intervals must be less than or equal to the programmed JUNCTIONAL AV LIMIT.

2.3 Tachyarrhythmia Redetection / Acceleration

The Tachos DR - Atrial Tx offers independently programmable settings for determining if tachyarrhythmias remain (redetection) or if the arrhythmia has accelerated into a higher rate zone (acceleration) after therapy has been delivered. The redetection and acceleration checking routines allow the Tachos DR - Atrial Tx to determine the next therapy sequence to be delivered by the ICD if the initial therapy has been unsuccessful at terminating the arrhythmia.

Tachyarrhythmia redetection and episode termination criteria are based on cardiac cycle length and number of intervals. Following delivery of any tachyarrhythmia therapy (VT, AT, AF or VF), the resulting cardiac rhythm is evaluated. The appropriate rate zone redetection counters or the episode termination counters are incremented for each detected post-therapy cardiac event. The cycle length and heart chambers of the cardiac rhythm determine which counter is incremented.

The Tachos DR - Atrial Tx is also able to redetect an arrhythmia if it has accelerated using the programmed Redetection Count. The interval and stability (if Smart Redetect VT/VF are programmed ON) ranges are identical to the initial detection parameter values for each arrhythmia class.

2.3.1 Acceleration

A ventricular tachyarrhythmia is determined to have accelerated from VT-1 to VT-2 if, during redetection, the average of four most recent measured R-R intervals is within the VT-2 zone. An atrial tachyarrhythmia is determined to have accelerated from AT–1 to AT–2 if, during redetection, the criterion for the AT–2 zone is met.

A ventricular tachyarrhythmia is determined to have accelerated from VT to VF if a number of R-R intervals equal to the programmed Redetection Count are detected within the VF zone during redetection. An atrial tachyarrhythmia is determined to have accelerated from AT to AF if a number of P-P intervals equal to the programmed Redetection Count are detected within the AF zone during redetection.

2.3.2 Redetection

If SMART Detection™ is activated for initial detection, it may also be programmed ON for redetection after VT or VF as well. The following criteria are programmable during arrhythmia redetection.

2.3.2.1 SMART Redetection after VT

With SMART Redetect after VT programmed ON, both atrial and ventricular signals are used for redetection after initial detection of VT. SMART Detection™ will function identically as in initial VT detection. The VT Sample Count is separately programmable for redetection.

2.3.2.2 SMART Redetection after VF

The SMART Detection™ Redetect for VF parameter provides SMART Detection™ discrimination during redetection of an arrhythmia initially detected in the VF Zone. This feature is designed to avoid unnecessary therapy when a VF shock induces an atrial fibrillation that conducts to the ventricle at a rate that meets the VT rate criterion.

2.3.2.3 Redetection Count

With SMART Redetect after VT/VF programmed OFF, only interval length is used for redetection. The interval length must be within applicable tachyarrhythmia zones to increment the Redetection Counter.

2.3.2.4 VF Redetection Limit

VF Redetect limit allows an on-going ventricular arrhythmia to be redetected at a rate lower than initial detection in the VF zone. This may be useful if a previous VF therapy attempt results in slowing the ventricular rate below the initial VF cutoff limit. VF Redetect limit effectively lowers the zone limit for all VF redetection within a single episode.

2.3.3 Tachyarrhythmia Termination

Termination of a tachyarrhythmia episode (atrial or ventricular) is declared when a programmed number of consecutive sensed intervals, equal to the applicable Termination Count (A or V) are classified in the sinus rate zone.

2.4 Tachyarrhythmia Therapy

The Tachos DR - Atrial Tx offers a wide choice of therapy options that can be tailored to meet each specific patient's needs. Multiple therapies can be combined to provide a broad spectrum of treatment options.

2.4.1 Therapy Options

The Tachos DR - Atrial Tx offers independent programming of two ATP sequences and up to six shock therapies for each detected episode in each VT class. In a two-zone configuration, VT-1 is always the lowest programmed VT rate and VT-2 is the higher VT rate. The therapies for the VT-1 class are defined as ATP1, ATP2 and Shock. Therapies for VT-2 are defined as ATP3, ATP4 and Shock.

In the VF zone, Tachos DR - Atrial Tx can be programmed to deliver either six or eight defibrillation shocks.

Tachos DR - Atrial Tx also offers two ATP sequences and up to two shock therapies for each episode detected within each AT class. The therapies for the AT–1 class are defined as ATP1, ATP2 and Shock. The therapies for the AT–2 class are defined as ATP3, ATP4 and Shock. The ATP4 therapy consists of high frequency bursts.

In the AT-2 zone, Stability is used to optimize therapy based on the type of detected atrial arrhythmia (i.e., if the rate is unstable ATP therapy is skipped and programmed shock therapy is delivered). This parameter is separately programmable from, and operates entirely independent of, the Stability parameter in the ventricular tachycardia zones.

In the AF zone, Tachos DR - Atrial Tx offers high frequency bursts with programmability for up to ten bursts available. Defibrillation shocks, with the same configuration as ventricular fibrillation shocks, are also available to treat arrhythmia detected within the AF zone.

Atrial therapy may be delivered either automatically upon detection or delayed within a programmable time window, to allow the AT or AF to spontaneously terminate.

2.4.2 Therapy Progression

By design, the Tachos DR - Atrial Tx will deliver more aggressive therapy for each successive attempt within a single detected episode. Therefore, the device will not deliver ATP1 therapy following ATP2 therapy, and will not deliver any ATP therapy following a high voltage defibrillation shock. Ventricular therapy is always given precedence over atrial therapy.

Therefore, if a ventricular arrhythmia is detected during treatment of an atrial therapy, then all atrial therapy is halted and ventricular therapy initiated. Furthermore, once ventricular therapy has started, no atrial therapy will be delivered until ventricular arrhythmia termination. When the ventricular arrhythmia has terminated, the atrial arrhythmia is also considered terminated. Subsequent attempts to detect the atrial arrhythmia will use the initial detection criteria (or after the SVT therapy idle has expired) and restart the atrial therapy regimen.

For example, a 10 joules defibrillation shock is delivered for an arrhythmia detected in the VT-2 zone and results in a deceleration of the VT so that it is subsequently redetected in the VT-1 zone. At that point, the Tachos DR - Atrial Tx would continue with shock therapy, but all shocks programmed at less than 10 joules would be delivered at an energy of 10 joules.

If a defibrillation shock is delivered but does not terminate the arrhythmia, the next shock will always have the same or higher energy than the last delivered shock.

2.4.3 AT-1 and VT-1 Therapy Delays

Therapy delay parameters are separately programmable for both AT–1 and VT–1, detection zones. These delays are designed to reduce therapy in certain patients by allowing the tachyarrhythmias to spontaneously terminate. These delays have no affect on the detection algorithms. After detection of an arrhythmia within one of the zones (AT–1 or VT–1), therapy is withheld for a programmable duration. After the delay, the arrhythmia is reevaluated based on rate and the Redetection Count number. If the arrhythmia persists, then therapy will proceed as programmed. If evaluation determines that the arrhythmia has terminated, therapy is cancelled.

2.4.4 Antitachycardia Pacing Schemes

ATP therapy for each tachyarrhythmia zone may be programmed with a wide range of pacing schemes.

2.4.5 ATP Pacing Parameters

ATP Therapy may be programmed differently for treated arrhythmias designated AT-1, AT-2, VT-1 or VT-2 with parameters as defined below:

ATP Type - defines the sequence type for delivery of ATP pulses. BURST is a series of pulses delivered with a consistent interval between each pulse. RAMP is a series of pulses delivered with decreasing intervals between each pulse of the burst.

Number of Bursts - defines the number of sequences of ATP pulses.

Number of Pulses - defines the number of ATP pulses in each sequence.

ATP Coupling (R1-S1 or P1-S1) - duration from sensed ventricular event to the first pacing pulse of ATP attempt (for ventricular ATP, R1-S1) and from the sensed atrial event to the first pacing pulse of the ATP attempt (for atrial ATP, P1-S1), used for ATP synchronization.

S1-S1 Interval - duration from first, to second, pacing pulses of the initial ATP interval.

Scan Decrement (S1-S1 Scan) - intervals will decrease by the programmed value between subsequent ATP attempts after the first attempt.

Burst Decrement (S1-S1 Step) - subsequent intervals will decrease within each ATP attempt by the programmed value to create a Ramp scheme.

Add 1 - Additional pacing pulses may be added between ATP attempts.

NOTE:

All intervals may be programmed as absolute values or adaptive values (based on a percentage of the last detected interval average).

Ventricular ATP Therapy

The following ventricular ATP Therapy parameters are applicable for treating arrhythmias designated VT-1 and VT-2 and are not separately programmable for each arrhythmia classification:

- Minimum ATP Interval - defines the minimum interval between ATP pulses.
- ATP Amplitude - defines the voltage amplitude for each ATP pulse.
- ATP Pulse Width - defines the pulse width for each ATP pulse.
- ATP Time-out – A timer that begins to decrement after the initial ventricular ATP is delivered (VT-1 zone). If further therapy is required after the timer has expired, the system advances to the programmed shock therapy for the applicable VT zone. Therapy continues until arrhythmia termination or all programmed therapy (in the applicable zone) has been delivered. Arrhythmia acceleration to VT-2 or VF will allow additional therapy to be delivered.

Atrial ATP Therapy

The following atrial ATP Therapy parameters are applicable for treating atrial tachyarrhythmias designated AT-1 and AT-2 and are not separately programmable for each arrhythmia classification but are separately programmable between the atrium and ventricle:

- Minimum ATP Interval - defines the minimum interval between ATP pulses.
- ATP Amplitude - defines the voltage amplitude for each atrial ATP pulse.
- ATP Pulse Width - defines the pulse width for each atrial ATP pulse.
- ATP Ventricular Support - If ventricular support is "OFF", then all atrial ATP schemes will be delivered using the AOO pacing mode. If the ventricular support is "ON", then atrial ATP intervals will be delivered using a "DDD-like" pacing mode where atrial ATP pacing events will be delivered as programmed and tracked at an upper limit of 80 ppm (750ms) and an AV delay of 75 ms. For the HF Burst therapy, ventricular support is consistently provided at the programmed basic rate. This provides ventricular support rate based on the rate of the atrial ATP.
- ATP Ventricular Support Rate – pacing rate of ventricular support during atrial ATP.

2.4.6 ATP Help

ATP Help is a useful tool to assist the physician in choosing and confirming appropriate ATP programming. When the ATP help button is pressed, a histogram of the chosen scheme is shown.

2.4.7 High Frequency Burst Therapy

The following programmable parameters of the HF Burst therapy are available for treating atrial arrhythmias in the AT-2 and AF zones. Atrial High Frequency (HF) Burst Therapy consists of a series of pacing pulses delivered at a rate of 42 Hz (i.e. a pulse is delivered every 24 ms). HF Burst Therapy is a relatively painless alternative to shock therapy for terminating atrial fibrillation. The efficacy of the therapy is dependent on a number of parameters and patient specific

- HF Burst - The number of HF Bursts is programmable from 1 to 10 in a sequence.
- HF Duration - The length of each HF Burst in seconds is programmable to allow bursts of up to 29 seconds.

2.4.8 Shock Therapy

Shock Therapy can be delivered with or without reconfirmation after the high energy capacitors have been charged. The first two shock energies in each shock sequence have independently programmable Shock Energy. The remaining shock therapies are non-programmable and predetermined to deliver 30 joules. All shocks are synchronized to the first R-wave or paced event after the arrhythmia has been detected and the decision to deliver therapy has been made.

PRECAUTION

Shock Impedance - If the shock impedance is less than twenty-five ohms, reposition the lead system to allow a greater distance between the electrodes. Never implant the device with a lead system that has measured shock impedance as less than twenty-five ohms. Damage to the device may result.

Defibrillation Threshold - Be aware that changes in the patient's condition, drug regimen, and other factors may change the defibrillation threshold (DFT), which may result in non-conversion of the arrhythmia post-operatively. Successful conversion of ventricular fibrillation or ventricular tachycardia during arrhythmia conversion testing is no assurance that conversion will occur post-operatively.

Atrial shock therapy has separately programmable parameters to further control the use of shocks to treat atrial arrhythmias including:

1. **Atrial Maximum Shock Energy –** limits the energy for each atrial shock to a maximum programmable value.
2. **Atrial Shock Mode –** allows shocks in response to detected atrial arrhythmias.

3. **Atrial shock Delay** – postpones atrial shocks in an attempt to allow the atrial arrhythmias to self-terminate.
4. **Atrial start window** – signifies the time of day when atrial shocks may be delivered in order to deliver atrial shocks when the patient is normally inactive.
5. **Atrial window duration** – signifies the length of time, after the atrial start window, when atrial shocks may be delivered.

2.4.9 Shock Therapy Parameters

The following parameters are separately programmable for the shock therapy of each arrhythmia classification including AT-1, AT-2, AF, VT-1, VT-2 and VF therapies. The shock polarity parameter is used for all programmed shocks to assure consistent shock delivery.

Number of Shocks

The Number of Shocks parameter defines the total number of shock attempts per zone (AT-1, AT-2, AF, VT-1, VT-2 or VF). For each AT or AF zone, up to 2 shocks may be delivered, if necessary. For each VT zone, up to 6 shocks may be delivered, if necessary. For the VF zone up to 8 shocks may be delivered.

Reconfirmation

In the nominal setting (Reconfirmation = YES), the device will reconfirm the presence of an arrhythmia after completion of charging and prior to delivering each programmed shock therapy. If Reconfirmation is turned OFF, a shock therapy will be delivered upon completion of charging. If any programmed shock is aborted, then the second attempt of the shock will be committed (delivered without confirmation). Therefore, two successive shocks cannot be aborted.

The ventricular reconfirmation algorithm will deliver a shock if two out of three intervals with a rate faster than the lowest programmed tachyarrhythmia zone are detected within the reconfirmation window after charging is completed. The atrial reconfirmation algorithm will deliver the shock if the average atrial rate during the reconfirmation period is within the atrial detection zone. Alternatively, the shock will also be delivered if no sensed events are detected. In all other cases, the shock will be aborted.

If reconfirmation is programmed to NO, then the shock will be delivered immediately after the charge cycle without reconfirming the presence of the tachyarrhythmia.

Reconfirmation Type

The Reconfirmation Type determines the length of the shock reconfirmation window. The reconfirmation type is nominally programmed to NORMAL, meaning that the reconfirmation window starts at the end of shock charging and extends four tachycardia intervals. The four tachycardia intervals are defined by the slowest tachyarrhythmia zone programmed.

If the device is programmed only to a VF zone and the VF rate is variable (or there is signal dropout), it may be desirable to program the reconfirmation type to EXTENDED to avoid inappropriately aborted shocks. The EXTENDED option will increase the reconfirmation window to eight times the tachycardia interval length.

Shock Waveform

All shocks utilize a standard biphasic waveform. The waveform starts at the calculated voltage, based on the programmed energy level. After an exponential discharge through the lead system to 40% of the initial charge voltage, the shock changes polarity and discharges to 20% of the initial charge voltage. **Figure 6** provides a pictorial representation of the biphasic waveform.

	Phase 1	Phase 2
Begin	100%	40%
End	40%	20%

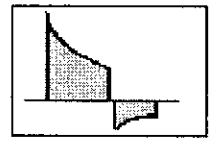


Figure 6. Biphasic Waveform

Shock Energy

The Shock Energy is programmable in 1 joule steps from 1.0 to 30 joules. The energy delivered is equal to the programmed energy. The first two shocks in each shock therapy sequence have programmable shock energies. After the first two shocks, all remaining shocks in each ventricular therapy sequence are fixed at maximum energy (30 joules).

Shock Polarity

The polarity of the shock therapy may be programmed and changed non-invasively. The STANDARD polarity configures the HV 1 port as the negative electrode and the HV 2 port and the outer housing as the positive electrode for the first phase of the shock. REVERSED polarity will reverse the electrical polarity of both of the connector ports and the housing. As a shared parameter, polarity applies to all programmed shocks.

2.4.10 SVT Therapy Idle and SVT Reevaluation Idle

The SVT Therapy Idle and SVT Reevaluation Idle work together to reduce the chances of atrial therapies initiating or reinitiating ventricular arrhythmias. Following each atrial therapy, the cardiac rhythm is evaluated during the programmed SVT Reevaluation Idle time. If a VT or VF arrhythmia is detected within this time, the ventricular arrhythmia will be treated as programmed. However, if an ongoing or subsequent atrial arrhythmia develops within the SVT Therapy Idle time (after ventricular arrhythmia termination) programmed therapy will be postponed or cancelled. If the atrial arrhythmia is sustained throughout the programmed SVT Therapy Idle time and no ventricular tachyarrhythmia is detected, then therapy will be initiated at the end of the idle time. If the atrial arrhythmia self-terminates within the SVT Therapy Idle, therapy is canceled.

2.4.11 Forced Termination Timer

With the VT-1 zone programmed ON and the VT-1 criteria met or if secondary therapy is withheld due to Smart Detection™ after VT or VF, it may be necessary to force termination of the episode. Expiration of the programmable Forced Termination Timer allows the Tachos DR - Atrial Tx to detect and provide therapy for subsequent tachyarrhythmias.

2.5 Bradycardia Therapy

The Tachos DR - Atrial Tx has independently programmable dual chamber bradycardia and post-shock bradycardia pacing functions. The post-shock bradycardia parameters may be programmed to higher rates or output values for the period following a delivered shock, without compromising the longevity of the ICD for patients who require chronic bradycardia pacing. The post-shock programmable values are presented in a separate subsection from the normal bradycardia support values.

2.5.1 Bradycardia Pacing Modes

The Bradycardia Pacing Mode may be programmed to DDDR, DDIR, VDDR, VVIR, DDD, DDI, VDD, VVI, AAI, AOO or OFF.

The basic rate timer is started by a sensed or paced event. A sensed event outside of the refractory period inhibits pacing and resets the lower rate time; in the absence of a sensed event, a pacing pulse will be delivered at the end of the lower rate interval.

The modes that contain an "R" in their designation are rate-adaptive modes. These modes are functionally the same as the corresponding non-rate-adaptive modes, except that the pacing rate will be automatically adjusted to take into account the current load on the patient's heart in response to increased physical activity.

2.5.2 Basic Rate

The rate is the pacing rate in the absence of a patient's intrinsic rhythm. This rate may be independently programmed for normal and post-shock bradycardia pacing.

2.5.3 Night Rate

To reduce the pacing rate in an attempt to match the decreased metabolic needs during sleep the Tachos DR - Atrial Tx can be programmed to Night Mode. When Night Mode is active, the pacing rate automatically decreases to the programmed NIGHT RATE during the nighttime hours.

At the programmed start time (NIGHT BEGINS), the rate gradually decreases to the night rate. When the internal clock reaches the programmed end time (NIGHT ENDS), the pacing rate gradually changes to the programmed basic rate. The rate changes in ppm/s as a function of the Sensor Gain decrease and increase parameters.

NOTE:

The Night Mode time is based on the programmer clock. Therefore, the programmer time should be checked prior to device programming. If a patient travels across different time zones, the Night Mode time may require adjustment.

2.5.4 Rate Adaptation

WARNING

Rate-Adaptive Pacing – Use rate-adaptive pacing with care in patients unable to tolerate increased pacing rates.

Tachos DR - Atrial Tx allows the selection of four rate-responsive pacing modes (DDDR, VDDR, DDIR and VVIR). These modes allow the ICD's bradycardia therapy function to adapt the pacing rate to increasing or decreasing patient activity, based on data collected from a motion sensor within the ICD. Separately programmable criteria allow the clinician to control the rate of increase and decrease of pacing, as well as the sensitivity of the sensors.

2.5.5 Sensor Gain and Threshold

The Sensor Gain defines how much the sensor signal is amplified before it is transformed to a rate change. When the Sensor Gain is low (e.g., 2), a great deal of exertion is needed to cause a significant change in sensor output (and an equal change in the pacing rate). When the Sensor Gain is high (e.g., 18), little exertion is needed to increase the sensor output. Ideally, the gain is programmed so the maximum desired pacing rate during exercise, occurs at a maximum exertion level.

The device ignores all activity that occurs below the Sensor Threshold because the Sensor Threshold defines the lowest sensor output that initiates a change in the pacing rate. Five different threshold settings are available including; VERY LOW, LOW, MEDIUM, HIGH, and VERY HIGH. When the threshold is programmed optimally, the basic rate is the effective rate while the patient is not moving (at rest).

2.5.6 Rate Increase / Decrease

The Rate Increase and Decrease parameters work with the Sensor Gain to determine how quickly pacing rate increases or decreases occur with changes in the sensor output.

2.5.7 Maximum Sensor Rate

Regardless of the sensor output, the sensor-driven pacing rate never exceeds the programmable Maximum Sensor Rate. The maximum sensor rate only limits the pacing rate during sensor-driven pacing.

2.5.8 Auto Sensor Gain

The Tachos DR - Atrial Tx offers Automatic Sensor Gain settings, which allows the Sensor Gain parameter to be adjusted automatically.

When the Automatic Sensor Gain is activated, the pulse generator samples the sensor-indicated rate. If, during the 24-hour period beginning at midnight, the total time recorded at maximum sensor rate exceeds 90 seconds, the sensor gain setting is reduced by one step. The sensor gain will be increased by one step after 7 consecutive days during which the time recorded at maximum sensor rate is less than 90 seconds each day.

2.5.9 Upper Tracking Rate

In the atrial tracking modes (DDDR, VDDR, DDD and VDD), ventricular pacing tracks atrial pace/sense events. The maximum tracking rate (ventricular pacing rate) is limited by the Upper Tracking Rate.

2.5.10 Dynamic AV Delay

The AV Delay defines the interval between an atrial paced or sensed event and the ventricular pacing pulse. If the pulse generator is programmed to a dual-chamber, sensing mode, an intrinsic ventricular event falling within the AV Delay will inhibit the ventricular pacing pulse. If not contraindicated, a longer AV Delay can be selected to preserve intrinsic AV conduction.

Dynamic AV Delay is where the AV Delay is varied depending on the spontaneous atrial rate. Dynamic AV Delay provides independent selection of AV Delays from five rate ranges at preset AV Delay values. In addition, the AV Delay after atrial pace events can be differentiated from the atrial sense events for dual chamber pacing modes.

In addition to selecting the preset values (low, medium, and high) with the Dynamic AV Delay window, the Dynamic AV Delays may be programmed individually or to a fixed AV Delay.

The AV Delay feature includes an AV Delay shortening option (sense compensation) for dual chamber pacing modes. When enabled, the AV Delay is shortened by 30 ms from the programmed value after an intrinsic atrial sensed event.

The Dynamic AV Delay is intended to mimic physiologic-shortening of the AV Delay with increasing heart rate.

2.5.11 Pulse Amplitude

The Pulse Amplitude parameters, both atrial and ventricular, define the amplitude in volts of the pacing pulses. The pulse amplitude is independently programmed for normal and post-shock bradycardia pacing.

2.5.12 Pulse Width

The Pulse Width parameters, both atrial and ventricular, define the duration of the pacing pulses. The pulse width is independently programmed for normal and post-shock bradycardia pacing.

2.5.13 Post Ventricular Atrial Refractory Period (PVARP)

Immediately following each sensed or paced ventricular event, an atrial refractory period is started. Atrial signals are ignored during this time for bradycardia timing purposes to prevent the ICD from sensing inappropriate signals. However, all sensed atrial signals that occur within the PVARP are used for atrial tachyarrhythmia classification.

2.5.14 PVARP Extension

Extends the Post Ventricular Atrial Refractory Period by the programmed interval.

2.5.15 Automatic Mode Switching

Mode switching is designed to avoid tracking of atrial arrhythmias. In the presence of a high atrial rate, the bradycardia pacing mode is automatically reprogrammed to a non-atrial tracking mode. The modes available during mode switching are as shown in Table 16.

Table 16: Mode Switching Modes

Programmed Mode	Converted Mode
DDDR	DDIR
DDD	DDIR DDI
VDDR	VVIR
VDD	VVIR VVI

Mode switching is initiated in atrial tracking modes when the atrial rate, defined by the non-programmable mode switch limit, (upper tracking rate +20 bpm) is achieved. However, mode switching will not occur until the Mode Switching Count criterion is also met (see 2.5.15.1 Mode Switching Count)

The mode reverts to the normal pacing mode when four consecutive slow intervals are sensed. Mode switching is not available during the post-shock pacing period.

NOTE:

Mode switch reversion may be delayed up to 60 seconds under certain conditions. The non-atrial tracking mode may remain in effect up to 60 seconds after the atrial rhythm has returned to a rate below the mode switch intervention rate.

2.5.15.1 Mode Switching Count

This is an up/down counter that controls the timing of mode switching. Each atrial event that exceeds the mode switch rate limit will increment the counter. When the atrial rate is slower than the limit, the counter decrements. The nominal Mode Switching Count is 4 intervals, but it can be programmed to 5, 6, 7, or 8 counts.

2.5.15.2 Mode Switching Mode

Programmable pacing mode that the device changes to during the high atrial rate (mode switch in progress).

2.5.15.3 Mode Switch Basic Rate

Whenever Mode Switching occurs, the device switches to a non-tracking mode and will provide bradycardia pacing support at the Mode Switch Basic Rate. Once Mode Switching is terminated, the permanently programmed pacing mode and programmed pacing rate are restored.

2.5.16 Noise Response

The Tachos DR - Atrial Tx response to detected noise is to deliver asynchronous pacing in the affected channel.

2.5.17 Post Shock Pacing

Separately programmable bradycardia pacing support is available with the ICD following shock therapy delivery. Because a delay in bradycardia pacing may avoid re-initiation of a tachyarrhythmia, after a short blanking period and post shock pause period, the ICD will begin bradycardia therapy at the post shock pacing rate, amplitude, and pulse width. Separate post-shock programming of the following parameters is available:

- Upper Tracking Rate
- Dynamic AV Delay
- Pacing Mode
- Basic Rate
- Pulse Width
- Pacing Amplitude
- PVARP
- PVARP Extension

The duration of post shock pacing can be modified by the Post-Shock Duration parameter. If bradycardia pacing is still required, standard bradycardia pacing parameters will be used at the completion of post-shock pacing. Mode switching is not available during Post-Shock Pacing.

2.6 EP Test Functions

When the EP test screen is active, the Tachos DR - Atrial Tx is able to automatically detect and treat atrial and ventricular tachyarrhythmias.

WARNING

Resuscitation Availability - Do not perform induction testing unless an alternate source of patient defibrillation such as an external defibrillator is readily available. In order to implant the ICD system, it is necessary to induce and convert the patient's ventricular tachyarrhythmias.

PRECAUTION

Manual Shocks – User-commanded shocks may be withheld if the ICD is already busy processing a manual command or the Battery Status is low.

2.6.1 Arrhythmia Induction Features

The ICD offers three arrhythmia induction methods for non-invasive EP testing. These include the following:

50 Hz Induction This feature consists of a large number of pulses delivered in rapid succession over a period of several seconds. The frequency of the pulses is 50 Hz and the duration of the burst can be defined by the user.

PES Induction delivers a burst of pacing stimuli followed by a programmable number of timed extra stimuli. The burst rate is independently programmable, as is the number of S1's. The interval between S1s and the remaining programmed extra stimuli (PES: S1 through S5 possible) is also programmable.

Shock on T induction mode allows tachyarrhythmia induction by means of a timed T wave shock delivered after a series of paced stimuli. Energy of the T wave shock, rate of the pulse train, and the shock coupling interval are all user defined.

Atrial DFT Testing In order to establish a clinically relevant atrial DFT, the following procedure was established and used during the clinical study. These are recommendations that will provide an improved atrial DFT baseline so that chronic atrial shock programming may be optimized.

Automatic atrial therapy should be programmed off during atrial DFT testing. If atrial therapy is programmed on, then atrial tachyarrhythmias that are induced from the EP test screen would receive a shock immediately after detection. In some cases, spontaneous atrial tachyarrhythmias might not receive shock therapy until several hours later. Therefore, BIOTRONIK recommends waiting at least 1 minute after atrial arrhythmia induction and then delivering manual shock therapy through the programmer to establish the atrial DFT. This method also allows more flexibility in delivery of subsequent atrial shocks if the first one is not effective. If the first shock is not effective, then subsequent shocks should be delivered in a step up manner under the arrhythmia is converted.

After induction of AF/AF, atrial conversion testing should be started at 6 joules. If the first shock fails to convert the arrhythmia, then subsequent shocks should be delivered at higher energies in increments of 2 joules. If the 6 joule shock converted the arrhythmia, then the arrhythmia should be induced again and conversion should be attempted starting with 4 joules. Continue as necessary to obtain a first shock success at the lowest possible energy. Whenever possible, use increments of 2 joules unless that energy has previously been tested.

The following bullets provide some examples of various testing sequences.

Example A

- Induce AF, deliver 6 J, converted to NSR
- Induce AF, deliver 4 J, converted to NSR
- Induce AF, deliver 2 J, not converted, deliver 3 J, converted to NSR

Example B

- Induce AF, deliver 6 J, not converted, deliver 8 J, converted to NSR
- Induce AF, delivery 7 J, not converted, deliver 8 J, converted to NSR

2.6.2 Manual Shock

The ICD can deliver a manual shock on demand through a programmer command in the EP test menu. To deliver a shock, place the wand over the device and select the Manual Shock button. A confirmation menu will appear and the shock command will be delivered upon selecting the Deliver Manual Shock button in this screen. After each manual shock, the EP test screen will display the shock lead impedance and shock charge time.

NOTE:

The shock lead impedance may not be automatically displayed on the EP Test Screen but is available from either the Episode History or System Status / Counters screens.

2.6.3 Test Shock

The ICD can deliver a 1 joule (R-wave synchronous) test shock on demand through a programmer command in the EP test menu. This shock is designed to measure the shock impedance and test the integrity of the shock electrodes of an implanted ICD lead.

WARNING

Resuscitation Availability - Do not perform induction testing unless an alternate source of patient defibrillation such as an external defibrillator is readily available. In order to implant the ICD system, it is necessary to induce and convert the patient's ventricular tachyarrhythmias.

PRECAUTION

Defibrillation Threshold - Be aware that the changes in the patient's condition, drug regimen, and other factors may change the defibrillation threshold (DFT) which may result in non-conversion of the arrhythmia post-operatively. Successful conversion of ventricular fibrillation or ventricular tachycardia during arrhythmia conversion testing is no assurance that conversion will occur post-operatively.

2.7 Special Features

WARNING

Unwanted Shocks – Always program the therapy status to DISABLED prior to handling the device to prevent the delivery of serious shocks to the patient or the person handling the device during the implant procedure.

2.7.1 Therapy Enabled

Interrogating the device and observing the Therapy section (upper right hand corner) of the main programming screen indicates the Therapy status (either ENABLED or DISABLED). The detection status can be changed by selecting the Therapy section of the main programming screen and selecting the desired setting from the resulting pop-up screen.

2.7.2 Capacitor Reforming

Shock charge times may be prolonged if the high voltage capacitors remain uncharged for an extended period of time. Conditioning (or re-forming) the capacitors by periodically charging them will help assure shorter charge times in those patients that do not regularly receive shock therapy. The ICD may be programmed to automatically re-form the capacitors after every 3, 6, 9, or 12 months or not at all (OFF). The capacitor reformation clock is reset following an automatic or manual capacitor re-form, or any device initiated maximum charging of the high voltage capacitors. BIOTRONIK recommends reforming the capacitors every 12 months.

An automatic or manually initiated capacitor reform fully charges the capacitors and then allows the capacitors to drain off through the internal circuitry of the ICD. No shock will be delivered to the patient. Throughout the re-formation process the ICD will provide bradycardia pacing support and tachyarrhythmia sensing and detection as programmed. If a tachyarrhythmia is detected during capacitor re-formation, the re-form process is aborted and therapy is available if required.

2.7.3 Pacing Threshold / Impedance

The test is activated as a temporary program with specific operation. Removal of the programmer head immediately stops the test and reactivates the permanent program.

NOTE:

Pacing Threshold - Testing of the pacing threshold by the ICD system should be performed with the pacing rate programmed to a value at least 20 ppm higher than the patient's intrinsic rate.

The following parameters are programmable during the pacing threshold test: Appropriate chamber and pacing mode, pacing rate, AV Delay (if appropriate), pulse amplitudes and pulse widths, number of pulses and automatic printing capabilities. The pacing modes available for the threshold test are AOO or AAI, VVI, DVI, or DDD. The pulse amplitude is easily adjustable during the threshold testing by selecting the desired value from the table. Pacing impedance can also be measured directly from the threshold test screen.

NOTE:

The impedance measurement has a tolerance of ± 20%.

2.7.4 Patient and Implant Data

The Patient and Implant data screens allow input of data regarding the patient name, demographics, implanting physician, date, devices implanted, location of the implant, and various physiologic measurements related to the implanted system. This information is transmitted to the ICD and resides in the device memory for later recall if needed.

2.7.5 System Status

Various device parameters can be monitored through this screen. Displayed data includes ICD information, charge circuit parameters, capacitor reform information, battery status and voltage, and lead information. The system status screen presents a large variety of information about the Tachos DR - Atrial Tx including:

- Battery status
- Serial number
- Device status
- Battery voltage
- Last pacing lead impedance (atrial and ventricle)
- Last shock charge time
- Last shock energy
- Last shock impedance
- Last full energy charge
  - Date
  - Charge time
- Total number of charges

2.7.6 Holter Memory

Various device information is available within this menu of information recorded within the ICD's memory. Several different programmer screens are available under the heading "Holter" including; detailed episode data, shock data, counters for various therapies and other events as well as additional information regarding the ICD's success in converting arrhythmias.

2.7.6.1 Episode History

The ICD stores a variety of useful diagnostic data about tachyarrhythmia episodes, which may be used to optimize tachyarrhythmia detection and therapy parameters. This diagnostic data includes detection counters, therapy counters, last delivered ATP and shock therapy, shock data memory, therapy history, and stored intracardiac electrograms.

Episode Details

Detailed information about each individual episode presented as a table of events ordered from most recently delivered to the first delivered. Each IEGM segment can be viewed from the episode detail sub-menu by selecting the View IEGM button. From this screen, an IEGM can be expanded, scaled, and scrolled to assist in a more accurate IEGM interpretation by enabling a closer examination of specific segments.

Stored IEGM

The ICD can store up to 32 minutes of dual chamber intracardiac electrograms (IEGMs) including the history and prehistory of the following events:

- Detection
- Redetection
- Terminations
- Manual Shocks
- AV Discrimination Success

The Holter memory is divided into 7, 15, 31, 63, or 127 event segments.

2.7.6.2 Shocks

The device history regarding high energy shocks is presented in a table format with the following information:

- Date
- Time
- Energy
- Charge time
- Impedance
- Type of shock

2.7.6.3 Counters

The device history regarding several therapy and detection parameters is presented in the "Counters" screen. This screen contains both the number of events since the last ICD memory clearance (with the date the memory was last cleared) and total since the device was implanted. The available parameters include:

Therapies

- Ventricular ATP Therapies
- VF Shocks
- VT Shocks
- HF ATP Bursts
- AF Shocks
- AT Shocks

Detection Episodes

- VT-1
- VT-2
- VF
- AT–1
- AT–2
- AF

Accelerations

- VT–1 to VT–2
- VT to VF
- AT–1 to AT–2
- AT to AF

2.7.6.4 Successes

The device history regarding the success of delivered therapies as well as the SMART Detection™ discrimination algorithm is displayed under the heading "Successes". This information includes the number of therapies delivered, successful, unsuccessful and aborted for the following:

- Ventricular ATP
- Ventricular Shocks
- Atrial ATP
- Atrial HFB
- Atrial Shocks

The number of therapies withheld due to SMART Detection™ is also included in a table format. With a single glance, this table shows the efficacy of all programmed therapies.

2.7.7 Real-time IEGM

The surface ECG is continuously displayed in the Overview screen, the Sensing screen and the EP test functions module. Real-time IEGMs are available in the EP tests and sensing / impedance screens.

The sensing / impedance screen allows automatic measurement of P-waves and R-waves. The sensing / impedance screen also allows a temporary bradycardia program to be sent to the ICD for evaluation of pacing parameters. IEGM markers are available for all sensed and paced events.

2.7.8 Brady Diagnostics

The ICD stores a variety of useful diagnostic data of the bradycardia history as described in the following sections.

2.7.8.1 Event Counters

The total number of atrial sensed, atrial paced, ventricular sense and ventricular paced events since the statistics package was initiated are available. The total percentage of time for each of the above listed events is also available.

2.7.8.2 Activity Report

The activity report provides information that can assist the physician in optimizing pacing and/or sensor parameters. This report contains the maximum sensor rate attained and the mean sensor rate.

2.7.8.3 Sensor Rate Histogram

The sensor rate histogram shows the percentage of time the sensor rate lies within given heart rate bins regardless if the sensor is used or not. The heart rate range is divided into nine segments ranging form 50 to 190 bpm.

3. Sterilization and Storage

The ICD is shipped in a storage box, equipped with a quality control seal and product information label. The label contains the model specifications, technical data, serial number, use before date, and sterilization and storage information.

The ICD and its accessories have been sealed in a container and gas sterilized with ethylene oxide. To assure sterility, the container should be checked for integrity prior to opening.

PRECAUTION

Device Packaging - Do not use the device if the device's packaging is wet, punctured, opened or damaged because the integrity of the sterile packaging may be compromised. Return the device to BIOTRONIK.

Re-sterilization - Do not re-sterilize and re-implant explanted devices.

Storage (temperature) - Store the device between 5° to 55°C (41° - 131° F) because temperatures outside this range could damage the device.

Storage (magnets) - To avoid damage to the device, store the device in a clean area, away from magnets, kits containing magnets, and sources of electromagnetic interference (EMI).

Temperature Stabilization - Allow the device to reach room temperature before programming or implanting the device because temperature extremes may affect initial device function.

Use Before Date - Do not implant the device after the USE BEFORE DATE because the device may have reduced longevity.

4. Implant Procedure

4.1 Implant Preparation

Prior to beginning the ICD implant procedure, ensure that all necessary equipment is available. The implant procedure requires the selected lead system (including sterile back-ups), the programmer with appropriate software, and the necessary cabling and accessories. The available cabling and accessories are as follows:

- PK44 - used to connect the TMS 1000^{PLUS} to implanted lead systems for complete testing of the lead systems during the implant procedure. The following adapters may be necessary:
  - Adapters PA-2/PA-3 - The PA-2 adapter is used to connect IS-1 compatible leads to the PK-44 cable. The PA-3 adapter is used to connect DF-1 compatible leads to the PK-44 cable.
  - Adapter PA-4 - used to connect the PK-44 cable to sensing and pacing leads while the stylet is still inserted.

The ICD System also has the following accessory available (at the discretion of the physician) for the implant procedure:

- Test housing that allows acute testing of the lead system prior to opening the sterile package.

Perform an interrogation of the Tachos DR - Atrial Tx. Ensure programmer operation, nominal device parameters and battery status is appropriate for a new Tachos DR - Atrial Tx ICD. Note that the battery status may appear lower than its true value when the ICD is not at body temperature. Program detection "Disable" prior to handling the Tachos DR - Atrial Tx ICD.

Sufficient training on the device and its associated components is required prior to implanting the Tachos DR - Atrial Tx. For additional information, training and training materials contact your BIOTRONIK representative.

WARNING

Lead Systems - The use of another manufacturer's ICD lead system may cause potential adverse consequences such as undersensing of cardiac activity and failure to deliver necessary therapy.

PRECAUTION

Blind Plug - A blind plug must be inserted and firmly connected into any unused header port to prevent chronic fluid influx and possible shunting of high energy therapy.

Connector Compatibility - ICD and lead system compatibility should be confirmed prior to the implant procedure. Consult your BIOTRONIK representative regarding lead/pulse generator compatibility prior to the implantation of an ICD system. For further information, please refer to **Appendix A**.

Pacemaker/ICD Interaction - In situations where an ICD and a pacemaker are implanted in the same patient, interaction testing should be completed. If the interaction between the ICD and the pacemaker cannot be resolved through repositioning of the leads or reprogramming of either the pacemaker or the ICD, the pacemaker should not be implanted (or explanted if previously implanted).

Programmed Parameters – Program the device parameters to appropriate values based on the patient's specific arrhythmias and condition.

Shock Impedance - If the shock impedance is less than twenty-five ohms, reposition the lead system to allow a greater distance between the electrodes. Never implant the device with a lead system that has a measured shock impedance of less than twenty-five ohms. Damage to the device may result.

4.2 Lead System Evaluation

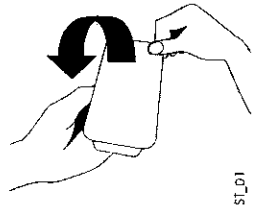
The ICD is mechanically compatible with DF-1 defibrillation lead connectors and IS-1 sensing and pacing lead connectors. IS-1, wherever stated in this manual, refers to the international standard, whereby leads and pulse generators from different manufacturers are assured a basic fit [Reference ISO 5841-3:1992]. DF-1, wherever stated in this manual, refers to the international standard [Reference ISO 11318:1993].

Refer to the appropriate lead system technical manual.

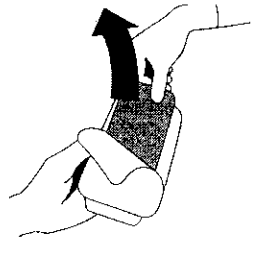
4.3 Opening the Sterile Container

The Tachos DR - Atrial Tx is packaged in two plastic containers, one within the other. Each is individually sealed and then sterilized with ethylene oxide.

Due to the double packing, the outside of the inner container is sterile and can be removed using standard aseptic technique and placed on the sterile field.



Peel off the sealing paper of the outer container as indicated by the arrow. Do not contaminate the inner tray.



Take out the inner sterile tray by gripping the tab. Open the inner tray by peeling the sealing paper as indicated by the arrow.

PRECAUTION

Device Packaging - Do not use the device if the device's packaging is wet, punctured, opened or damaged because the integrity of the sterile packaging may be compromised. Return the device to BIOTRONIK.

4.4 Pocket Preparation

Using standard surgical technique, create a pocket for the device either in the patient's pectoral or abdominal region dependent on patient anatomy. The device may be implanted either below the subcutaneous tissue or in the muscle tissue. The ICD should be implanted with the etched side facing up. The leads should be tunneled or surgically brought into the device pocket. If lead tunneling is performed, re-evaluation of the baseline lead signals, after tunneling is recommended.

PRECAUTION

Electrocautery - Electrosurgical cautery could induce ventricular arrhythmias and/or fibrillation, or may cause device malfunction or damage. If use of electrocautery is necessary, the current path and ground plate should be kept as far away from the pulse generator and leads as possible (at least 6 inches (15 cm)). The ICD system should be checked after any of medical procedures where exposure to EMI is likely, such as electrocautery.

4.5 Lead to Device Connection

The Tachos DR - Atrial Tx has been designed and is recommended for use with a defibrillation lead system having one IS-1 connector for ventricular sensing and pacing and up to two DF-1 connectors for delivery of shock therapy. A separate bipolar atrial lead with IS-1 connector is required for atrial sensing and pacing functions. **Figure 7** depicts the configuration of the header ports on the Tachos DR - Atrial Tx, where HV1 and HV2 are for DF-1 connectors, and A P/S and V P/S are for IS-1 connectors.

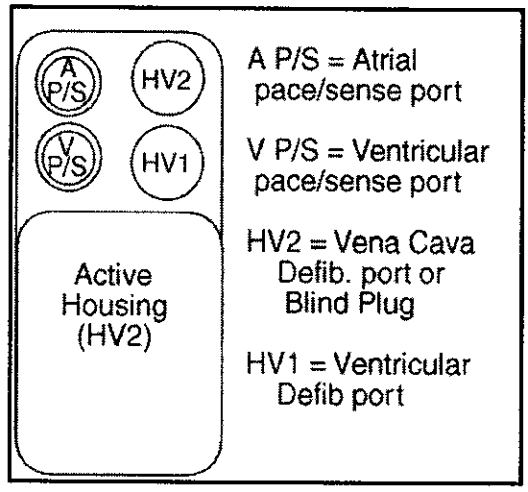


Figure 7. Header Ports

PRECAUTION

Connector Compatibility - ICD and lead system compatibility should be confirmed prior to the implant procedure. Consult your BIOTRONIK representative regarding lead/pulse generator compatibility prior to the implantation of an ICD system. For further information, please refer to **Appendix A**.

Setscrew Adjustment – Back-off the setscrew(s) prior to insertion of lead connector(s) as failure to do so may result in damage to the lead(s), and/or difficulty connecting lead(s).

Cross Threading Setscrew(s) – To prevent cross threading the setscrew(s), do not back the setscrew(s) completely out of the threaded hole. Leave the torque wrench in the slot of the setscrew(s) while the lead is inserted.

Tightening Setscrew(s) – Do not overtighten the setscrew(s). Use only the BIOTRONIK supplied torque wrench.

Sealing System – Be sure to properly insert the torque wrench into the perforation at an angle perpendicular to the connector receptacle. Failure to do so may result in damage to the plug and its self-sealing properties.

Far-field sensing of signals from the atrium in the ventricular channel or ventricular signals in the atrial channel should be avoided by appropriate lead placement, programming of pacing/sensing parameters, and maximum sensitivity settings. If it is necessary to lengthen A BLANK-V PACE or A BLANK-V SENSE, the parameter should be lengthened only long enough to eliminate far-field sensing as evidenced on the IEGMs. Extending either parameter unnecessarily may cause undersensing of actual atrial or ventricular events.

Refer to the following steps when connecting the leads to the device.

1. Confirm that the setscrews are not protruding into the connector receptacles. To retract a setscrew, insert the enclosed torque wrench through the perforation in the self-sealing plug at an angle perpendicular to the lead connector until it is firmly placed in the setscrew. Rotate

the wrench counterclockwise until the receptacle is clear of obstruction.

2. Insert the lead connector into the connector port of the ICD without bending the lead until the connector pin becomes visible behind the setscrew. Hold the connector in this position. If necessary, apply silicone oil only to the o-rings on the connector (not the connector pin).
3. Insert the enclosed torque wrench through the perforation in the self-sealing plug at an angle perpendicular to the lead connector until it is firmly placed in the setscrew.
4. Securely tighten the setscrew of the connector clockwise with the torque wrench until torque transmission is limited by the wrench.
5. After carefully retracting the torque wrench, the perforation will self-seal.

4.6 Blind Plug Connection

The ICD comes with a blind plug (pre inserted) for an unused header port. Refer to the following steps when connecting blind plugs to the device.

1. Confirm that the setscrews are not protruding into the connector receptacles. To retract a setscrew, insert the enclosed torque wrench through the perforation in the self-sealing plug at an angle perpendicular to the lead connector until it is firmly placed in the setscrew. Rotate the wrench counterclockwise until the receptacle is clear of obstruction.
2. Insert the blind plug into the connector port of the ICD until the connector pin becomes visible behind the setscrew.
3. Insert the enclosed torque wrench through the perforation in the self-sealing plug at an angle perpendicular to the connector until it is firmly placed in the setscrew.
4. Securely tighten the setscrew of the connector clockwise with the torque wrench until torque transmission is limited by the wrench.
5. After carefully retracting the torque wrench, the perforation will self-seal.

PRECAUTION

Blind Plug - A blind plug must be inserted and firmly connected into any unused header port to prevent chronic fluid influx and possible shunting of high energy therapy.

4.7 Pacemaker Interaction Testing

There are three situations in which pacemaker/ICD interaction testing is appropriate when:

- a pacemaker and an ICD are implanted at the same procedure
- an ICD is implanted in a patient with a chronic pacemaker
- a pacemaker is implanted in a patient with a chronic ICD

In each of these cases, the pacemaker and ICD may interact in such a way that the pacemaker could interfere with the classification of tachyarrhythmias by the ICD. The three possible mechanisms of interaction are listed below:

- During a tachyarrhythmia episode, the pacemaker may not detect the patient's tachyarrhythmia. In addition, the amplitude of the pacemaker pacing pulses may be large enough to cause the ICD to detect only the pacing pulses and not sense the underlying tachyarrhythmia. Therefore, the ICD would not provide appropriate anti-tachyarrhythmia therapy.
- The ICD may detect both the pacing pulses and the resulting ventricular response as separate signals (doubled count). The ICD might then classify the normal paced rhythm as a tachyarrhythmia and subsequently deliver therapy inappropriately.
- If the pacemaker experiences a sensing failure, a lead dislodgment, or lack of capture the ICD could sense the asynchronous pacing pulses along with the patient's normal sinus rhythm. The ICD may then classify the rhythm as a tachyarrhythmia and deliver inappropriate therapy.

The following test procedures should be performed during implantation of the ICD with a concomitant pacemaker. There are two separate procedures that must be completed.

Part 1

Verify that inappropriate therapy will not be initiated by oversensing of pacemaker pulses.

1. Program the detection status of the ICD to "DISABLED."
2. Keep the programming wand in place over the ICD to observe the intracardiac electrograms and markers when the pacemaker is inhibited.
3. Program the pacemaker's lower rate and AV Delay, if applicable, to values that ensure consistent pacing. Program the pacemaker to unipolar (or bipolar) pacing with the pacing amplitude and pulse width parameters at maximum values.
4. Observe the intracardiac electrograms and markers again. If either signal shows events that are oversensed, the ICD or pacemaker leads should be repositioned in order to minimize the amplitude of the pacing artifacts.
5. It may be necessary to reduce the pacing amplitude and pulse width settings of the pacemaker during testing to eliminate interaction with the ICD. If testing indicates a set of maximum allowable programmable parameters, it should be recorded in the patient's record for future reference, in the event that reprogramming is required.

Part 2

Verify that oversensing of pacemaker pulses during a tachyarrhythmia episode will not inhibit tachyarrhythmia therapy.

1. Program the pacemaker to a unipolar asynchronous pacing mode (V00 or D00) at maximum pacing amplitude and pulse width settings.
2. Program the detection status of the ICD to "ENABLED".
3. Induce ventricular fibrillation, from the EP Test screen.
4. Observe the intracardiac electrograms and the markers. **BE PREPARED TO DELIVER AN EMERGENCY SHOCK IF THE TACHYARRHYTHMIA IS NOT DETECTED AND TERMINATED BY THE ICD.**

5. If the ICD did not detect the tachyarrhythmia, reduce the pacemaker's output settings and repeat step 4 until maximum allowable pacemaker output settings are defined. The maximum allowable programming set should be recorded in the patient's records for future reference, should reprogramming be required.
6. After conversion testing is complete, interrogate the pacemaker to ensure that its programmed parameters have not been changed and that no damage was caused by delivery of therapy by the ICD.
7. Program the pacemaker to the appropriate pacing parameters based on the completed testing.

To reduce the possibilities of pacemaker/ICD interaction, it is recommended that:

- the ICD and pacemaker leads be places as far away as possible from one another
- the pacemaker leads with a short inter-electrode spacing be used
- the pacemaker be programmed to the lowest allowable amplitude and pulse width to ensure consistent, chronic capture
- the pacemaker must be programmed to the maximum sensitivity (without oversensing during a normal rhythm) to ensure pacing is inhibited during tachyarrhythmia episodes.
- the pacemaker be programmed to the minimum lower rate sufficient for the patient

NOTE:

The pacemaker must be returned to bipolar pacing after the pacemaker interacting testing (unipolar pacing is contraindicated).

PRECAUTION

Pacemaker/ICD Interaction - In situations where an ICD and a pacemaker are implanted in the same patient, interaction testing should be completed. If the interaction between the ICD and the pacemaker cannot be resolved through repositioning of the leads or reprogramming of either the pacemaker or the ICD, the pacemaker should not be implanted (or explanted if previously implanted).

4.8 Program the ICD

Program the ICD to appropriately treat the patient's arrhythmias and other therapy needs. The information obtained during the lead system evaluation should be helpful in tailoring the various parameters of the ICD to treat each individual patient. The detection status of the ICD may be activated for testing purposes once all of the lead connectors have been securely fastened in the device header ports. The physician shall be made aware of the program that is in effect after the patient leaves the office, by viewing the parameters displayed on the programmer screen after the device has been programmed and interrogated.

PRECAUTION

Programmed Parameters – Program the device parameters to appropriate values based on the patient's specific arrhythmias and condition.

Programmers - Use only BIOTRONIK programmers to communicate with the device (TMS 1000 PLUS, or EPR 1000 PLUS).

Defibrillation Threshold - Be aware that the changes in the patient's condition, drug regimen, and other factors may change the defibrillation threshold (DFT) which may result in non-conversion of the arrhythmia post-operatively. Successful conversion of ventricular fibrillation or ventricular tachycardia during arrhythmia conversion testing is no assurance that conversion will occur post-operatively.

WARNING

Unwanted Shocks – Always program the therapy status to DISABLED prior to handling the device to prevent the delivery of serious shocks to the patient or the person handling the device during the implant procedure.

4.9 Implant the ICD

The ICD may be placed in the pocket at this time. Place the device into the pocket with the etched side facing up. Carefully coil any excess lead length beside or above the ICD.

The pacing and sensing functions of the device should be evaluated. It is also recommended that at least one induction and device conversion be done prior to closing the pocket. This will ensure that the lead system has been securely connected to the device and has not changed position.

PRECAUTION

Connector Compatibility - ICD and lead system compatibility should be confirmed prior to the implant procedure. Consult your BIOTRONIK representative regarding lead/pulse generator compatibility prior to the implantation of an ICD system. For further information, please refer to **Appendix A**.

Pacemaker/ICD Interaction - In situations where an ICD and a pacemaker are implanted in the same patient, interaction testing should be completed. If the interaction between the ICD and the pacemaker cannot be resolved through repositioning of the leads or reprogramming of either the pacemaker or the ICD, the pacemaker should not be implanted (or explanted if previously implanted).

Shock Impedance - If the shock impedance is less than twenty-five ohms, reposition the lead system to allow a greater distance between the electrodes. Never implant the device with a lead system that has a measured shock impedance of less than twenty-five ohms. Damage to the device may result.

WARNING

Resuscitation Availability - Do not perform induction testing unless an alternate source of patient defibrillation such as an external defibrillator is readily available. In order to implant the ICD system, it is necessary to induce and convert the patient's ventricular tachyarrhythmias.

PRECAUTION

Defibrillation Threshold - Be aware that the changes in the patient's condition, drug regimen, and other factors may change the defibrillation threshold (DFT) which may result in non-conversion of the arrhythmia post-operatively. Successful conversion of ventricular fibrillation or ventricular tachycardia during arrhythmia conversion testing is no assurance that conversion will occur post-operatively.

NOTE:

Pacing Threshold - Testing of the pacing threshold by the ICD system should be performed with the pacing rate programmed to a value at least 20 ppm higher than the patient's intrinsic rate.

Prior to surgically closing the pocket, the telemetry contact should be evaluated to help ensure chronic programmer communication. Close the device pocket using standard surgical technique. As the final step at device implant and each patient follow-up, the permanent program should be retransmitted to the ICD.

Ensure the ICD detection status has been deactivated prior to using electrocautery.

Complete the Medical Device Registration Form provided with the ICD and return it to BIOTRONIK.

5. Follow-up Procedures

5.1 General Considerations

An ICD follow-up serves to verify appropriate function of the ICD system, and to optimize the programmable parameter settings.

In addition to evaluating the patient's stored therapy history and electrograms, acute testing of sensing and pacing is recommended. The physician shall be made aware of the program that is in effect after the patient leaves the office after each follow-up, by viewing the parameters displayed on the programmer screen after the device has been programmed and interrogated. As the final step at device implant and each patient follow-up, the permanent program should be retransmitted to the ICD. Due to longevity concerns, it is recommended the physician schedule a patient follow-up visit every 3 months.

WARNING

Resuscitation Availability - Do not perform induction testing unless an alternate source of patient defibrillation such as an external defibrillator is readily available. In order to implant the ICD system, it is necessary to induce and convert the patient's ventricular tachyarrhythmias.

5.2 Longevity

The service time of an ICD can vary based on several factors, including the number of charge sequences, programmed parameters, number of tachyarrhythmias detected, relative amount of bradycardia pacing required, pacing lead impedance, storage time, battery properties, and circuit operating characteristics. Service time is the time from beginning of service (BOS) to the elective replacement indication (ERI). To assist the physician in determining the optimum time for ICD replacement, a replacement indicator is provided that notifies the user that replacement within a certain period of time is required. Upon reaching ERI, the battery has enough energy left to continue monitoring for three months along with the ability to deliver at least six high-energy shocks. After this period, all tachyarrhythmia detection and tachyarrhythmia therapy is disabled.

PRECAUTION

Charge Time - When preparing a high energy shock the charge circuit stops charging the capacitors after 20 seconds, and delivers the stored energy as shock therapy. After the device reaches ERI the stored energy may be less than 30 joules per shock.

The service times from beginning of service (BOS) to elective replacement indication (ERI) are listed below in **Table 17**. All estimates assume pacing rate of 50 ppm with a pulse width of 0.5 ms and pulse amplitude of 2.4 volts and 500 ohm pacing impedance with all shocks at maximum energy (30 joules) at 37°C. It is assumed that the shocks are equally spaced throughout the life of the ICD. The estimates associated with 0% pacing support assume the ICD is sensing an intrinsic sinus rhythm at a rate of 70 bpm.

Table 17: Longevity Estimates

DDD Pacing Support	Shocks Per Year	Months
100 %	12	48.5
	4	56.6
	1	60.5
	0	61.9
50 %	12	51.1
	4	58.6
	1	62.6
	0	64.1
15 %	12	51
	4	60
	1	64.2
	0	65.8
0 %	12	51.4
	4	60.6
	1	65
	0	66.5

Each maximum-energy (30 joule), high voltage charging sequence reduces the longevity of the device by approximately 27 days.

Upon reaching ERI, the estimates associated with duration of ERI assume the ICD is sensing an intrinsic sinus rhythm at a rate of 70 bpm. The battery has enough energy left to continue monitoring for three months and to deliver six high-energy shocks. After this period the device is at EOS (End of Service) and requires explantation. Once at EOS, all tachyarrhythmia detection and therapy is disabled.

5.3 Explantation

Explanted ICDs, lead systems, and accessories may not be reused. Please complete the appropriate out of service (OOS) form and return it to BIOTRONIK with the explanted devices. All explanted devices should be sent either to the local BIOTRONIK representative or the BIOTRONIK home office for expert disposal. Contact BIOTRONIK if you need assistance with returning explanted devices. If possible, the explanted devices should be cleaned with a sodium-hyperchlorine solution of at least 1% chlorine and then washed with water prior to shipping.

The pulse generator should be explanted before the cremation of a deceased patient.

WARNING

Unwanted Shocks – Always program the therapy status to DISABLED prior to handling the device to prevent the delivery of serious shocks to the patient or the person handling the device during the implant procedure.

PRECAUTION

Device Incineration - Never incinerate the ICD due to the potential for explosion. The ICD must be explanted prior to cremation.

Explanted Devices - Return all explanted devices to BIOTRONIK.

6. Technical Specifications

The following are the technical specifications for the Tachos DR - Atrial Tx. The ranges are presented in the format:

x...(y)...z

where x = the lowest value, y = the increment, and z = the largest value.

Mechanical Properties

PARAMETER	VALUE RANGE
Dimensions	67 x 57 x 15 mm
Conducting Surface Area	77 cm^2
Volume	48 cc
Mass	84 g
Housing Material	Titanium
Header Material	Epoxy resin
Seal Plug Material	Silicone
Tachos DR - Atrial Tx Lead Ports	2 x 3.2 mm IS-1 Bipolar 2 x 3.2 mm DF-1

Parameters – Ventricular Tachyarrhythmia Therapy

PARAMETER	VALUE RANGE	STD PROGRAM	SAFE PROGRAM
Detection Parameters for VT Arrhythmia Classes			
Detection	ENABLED, DISABLED	EN	EN
Therapy	ENABLED, DISABLED	EN	EN
VT-1 Zone Limit	OFF,300...(10)... 600 ms 100 ... 200 bpm	360 ms	OFF
VT-2 Zone Limit	OFF,300...(10)... 590 ms 101 ... 200 bpm	OFF	OFF
Tachyarrhythmia	Sudden Onset Delta Stability SMART Detection	Stability Onset	Stability
VT Sample Count	12...(1)... 32	12	N/A
Safety Timer	OFF, 0:30...(0:15)... 10:00... (0:30) ... 30:00 min	OFF	OFF
Safety Timer Mode	TOTAL, SPECIFIC	TOTAL	TOTAL

PARAMETER	VALUE RANGE	STD PROGRAM	SAFE PROGRAM
Sudden Onset Delta	OFF, Absolute: 30...(10) ...500 ms Adaptive: 10... (5) ... 90%	20%	N/A
Stability	Adaptive: 5... (1) ...30 %	12%	12%
Smart Detection	ON, OFF	ON	N/A
Smart Decrement	0.25, 0.5, 0.75, 1.0	0.25	N/A
PR Regularity	5...(5)...300 ms	DFLT	N/A
1:1 Active Discrimination	OFF, 6 ... (1) ... 32	OFF	N/A
Number of Extra Stimuli	4 ... (1) ... 12	N/A	N/A
Initial Prematurity	40...(10) ...150 ms	N/A	N/A
Incremental Prematurity	5...(5) ...60	N/A	N/A
Minimum R-S1 Interval	150...(10) ...400 ms	N/A	N/A
Tolerance for Antegrade	8 ... (4) ... 32	N/A	N/A
Retrograde Confirmation at	2 ... (1) ... 12	N/A	N/A
Change Before Repeat	20...(5) ...100 ms	N/A	N/A
Detection Parameters for VF Class			
VF Zone Limit	OFF, 250...(10)...400 ms 150 ... 240 bpm	300 ms	300 ms
Number of X	5 ... (1) ... 25	8	8
Number of Y	8 ... (1) ... 32	12	12
Atrial Detection Refractory Period	102 ms	102 ms	102 ms
Ventricular Detection Refractory Period	121 ms	121 ms	121 ms
Redetection			
Redetection Count	12...(1)...31	12	12
VF Redetect Limit	OFF,250...(10)...600 ms 100...240 bpm	OFF	DFLT
SMART Redetect for VT	ON, OFF	OFF	N/A
SMART Redetect for VF	ON, OFF	OFF	N/A
Termination Count	6...(1)... 31	6	6

PARAMETER	VALUE RANGE	STD PROGRAM	SAFE PROGRAM
Forced Termination Timer	OFF, 1...(1)...15 min	OFF	N/A
Store AV Success Records	YES, NO	YES	N/A

Parameters – Atrial Tachyarrhythmia Therapy

PARAMETER	VALUE RANGE	STD PROGRAM	SAFE PROGRAM
Detection Parameters for Atrial Tachyarrhythmia Classes			
Detection	ENABLED, DISABLED	DIS	DIS
Therapy	ENABLED, DISABLED	DIS	DIS
AT–1 Zone Limit	OFF,300...(10)... 500 ms 120 ... 200 bpm	OFF	OFF
AT–2 Zone Limit	OFF, 200...(10)... 400 ms 150 ... 300 bpm	N/A	N/A
Tachyarrhythmia	AT–1 Onset Stability	N/A	N/A
AT Sample Count	12...(1)... 63	N/A	N/A
AT-1 Onset	Absolute: 30...(10)...500 ms Adaptive: 10...(5)...90%	N/A	N/A
Stability	Adaptive: 5... (1) ...30 % Absolute: 20...(10)...180 ms	N/A	N/A
Detection Parameters for AF Class			
AF Zone Limit	OFF, 150...(10)...300 ms 200 ... 400 bpm	OFF	OFF
Number of X	18 ... (1) ... 64	N/A	N/A
Number of Y	33 ... (1) ... 64	N/A	N/A
Redetection			
Redetection Count	12...(1)...67	N/A	N/A
AF Redetect Limit	OFF,150...(10)... 500 ms 120...240 bpm	N/A	N/A
Junctional AV	OFF, 20...(5)...100	N/A	N/A
All Junctional	ON, OFF	N/A	N/A
AF/Afl Decrement	0.25, 0.5, 0.75, 1	N/A	N/A
Termination Count	12...(1)... 63	N/A	N/A

Bradycardia Therapy

PARAMETER	VALUE RANGE	STD PROGRAM	SAFE PROGRAM
Mode	DDDR, DDIR, DDD, DDI, VDDR, VVIR, VDD, VVI, AOO, AAI, OFF	VVI	VVI
Basic Rate	31...(1)...88...(2)... 110 ppm	50 ppm	70 ppm
Night Rate	OFF, 31...(1)...88...(2)... 110 ppm	OFF	OFF
Night Rate Begin	00:00...(00:15)...23:15	N/A	N/A
Night Rate End	00:00...(00:15)...23:15	N/A	N/A
Amplitude (V or A)	0.1...(0.1)...4.8...(0.2)... 7.2 V	2.4 V	7.2 V
Pulse Width (V or A)	0.20, 0.30, 0.40, 0.50, 0.80, 1.00, 1.50 ms	0.50 ms	1.50 ms
Upper Tracking Rate	80, 100...(10)...140, 160 ppm	110 ppm	110 ppm
Mode Switch	ON, OFF	OFF	OFF
Mode Switch Limit	UTR+20 bpm	N/A	N/A
Mode Switch Basic Rate	31...(1)...88...(2)... 110 ppm	N/A	N/A
Mode Switch Mode	DDIR, DDI, VVIR, VVI	N/A	N/A
Mode Switch Count	4, 5, 6, 7, 8	N/A	N/A
PVARP	200...(5)...500 ms	N/A	N/A
PVARP Extension	125 ...(5)...300 ms	N/A	N/A
Dynamic AV Delay	low, medium, high, fixed	N/A	N/A
Sensor Gain	1.0...40.0	N/A	N/A
Maximum Sensor Rate	80 ...(5)...180 ppm	115 ppm	N/A
Sensor Threshold	Very Low, Low, Medium, High, Very High	N/A	N/A
Auto Sensor Gain	ON, OFF	OFF	OFF
Rate Increase	1, 2, 4, 8 ppm/sec	N/A	N/A
Rate Decrease	0.1, 0.2, 0.4, 0.8 ppm/sec	N/A	N/A

Additional Sensing Parameters

PARAMETER	VALUE RANGE	STD PROGRAM	SAFE PROGRAM
Atrial Max Sensitivity	0.250 ... (.125) ... 3.000	0.375	0.375
Ventricular Max Sensitivity	0.250 ... (.125) ... 3.000	0.500	0.500
T-wave Suppression	NORMAL, LONG QT, LARGE T, LONG QT and LARGE T	NORM	NORM
A Blank – V Pace	23...200 ms	23 ms	23 ms
A Blank – V Sense	0...120 ms	0	0
Early Far Field Tolerance	OFF, 8, 12, 16	8	8
Atrial Paced Refractory Period	150 ... (5) ... 400 ms	300 ms	300 ms
Ventricular Paced Refractory Period	250 ... (5) ... 400 ms	250 ms	250 ms

Post-Shock Bradycardia Therapy

PARAMETER	VALUE RANGE	STD PROGRAM	SAFE PROGRAM
Mode	DDDR, DDIR, DDD, DDI, VDDR, VVIR, VDD, VVI, AOO, AAI, OFF	DDD	DDD
Basic Rate	31...(1)...8...(2)...110 ppm	60 ppm	60 ppm
Dynamic AV Delay	low, medium, high, fixed	MED	MED
Amplitude	0.1 ... (0.1) ... 4.8...(0.2) ... 7.2 V	7.2 V	7.2 V
Pulse Width	0.20, 0.30, 0.40, 0.50, 0.80, 1.00, 1.50 ms	1.0 ms	1.50 ms
Upper Tracking Rate	80, 100 ... (10) ... 140, 160 ppm	120 ppm	120 ppm
PVARP	200...(5)...500 ms	N/A	N/A
PVARP Extension	125 ...(5)...300 ms	N/A	N/A
Post –Shock Duration	0:30... (0:15) ... 30:00 min	0:30	0:30
Post –Shock Pause	1...(1)...10	1	1

Basic ATP Therapy

PARAMETER	VALUE RANGE	STD PROGRAM	SAFE PROGRAM
ATP Type	OFF, BURST, RAMP	RAMP	N/A
Amplitude (A and V)	0.1 ... (0.1) ... 4.8...(0.2)... 7.2 V	7.2 V	N/A
Pulse Width (A and V)	0.20, 0.30, 0.40, 0.50, 0.80, 1.00, 1.50 ms	1.0 ms	N/A
Number of Bursts	1 ... (1) ... 10	3	N/A
Number of Pulses	1 ... (1) ... 25	5	N/A
ATP Coupling R1-S1	Absolute: 200...(10)...530 ms Adaptive: 70... (1) ...98 %	81%	N/A
S1-S1	Absolute: 200...(10)...530 ms Adaptive: 70... (1) ...98 %	81%	N/A
Minimum ATP Interval – Ventricle	200 ... (10) ... 300 ms	200 ms	N/A
Minimum ATP Interval - Atrium	150 ... (10) ... 300 ms	N/A	N/A
Step	0 ... (-5) ... -40 ms	N/A	N/A
Scan	0 ... (-5) ... -40 ms	N/A	N/A
Scan - Atrium	40 ... (-5) ... -40 ms	N/A	N/A
Add 1	ON, OFF	N/A	N/A
ATP Time-out	OFF, 0:30 ... (:15)... 2:00 ... (:30) ... 5:00 ...(1:00) ... 20:00	N/A	N/A
VT-1 Therapy Delay	0...(5)...20 seconds	0 sec	N/A

HF Burst Therapy

PARAMETER	VALUE RANGE	STD PROGRAM	SAFE PROGRAM
HF Bursts	1...(1)...10	N/A	N/A
HF Duration	1...(1)...6, 12, 17, 23, 29 seconds	N/A	N/A

Shock Therapy

PARAMETER	VALUE RANGE	STD PROGRAM	SAFE PROGRAM
Number of VT Shocks	0...(1)...6	5	N/A
Number of VF Shocks	6...(1)...10	6	6
Number of AT/AF shocks	0, 1, 2	0	0
Shock Waveform	Biphasic	Biphasic	Biphasic
Reconfirmation	YES, NO	YES	NO
Reconfirmation Type	NORMAL, EXTENDED	NORM	NORM
1st Shock Energy	1.0...(1)…16…(2)…30 joules	20 j-VT 30 j- VF	30
2nd Shock Energy	2.0...(1)…16…(2)…30 joules	20 j-VT 30 j- VF	30
Shock Polarity	STANDARD REVERSED	STD	N/A

Additional Atrial Therapy

PARAMETER	VALUE RANGE	STD PROGRAM	SAFE PROGRAM
Atrial Maximum Shock Energy	1.0...(1)...16...(2)...30 joules	N/A	N/A
Atrial Shock Mode	ON, OFF	N/A	N/A
Atrial Reconfirmation	YES, NO	N/A	N/A
Atrial Shock Delay	1, 30, 60 min, 2, 4, 8, 12 hours	28 min	28 min
Atrial Start Window	08:00...(01:00)...23:00	N/A	N/A
Atrial Window Duration	01:00...(01:00)...7:00, 24:00	N/A	N/A
SVT Reevaluation Idle	10...(5)...45 seconds	N/A	N/A
SVT Therapy Idle	4, 8, 12 hours	N/A	N/A
ATP Ventricular Support	ON, OFF	ON	N/A
ATP Ventricular Support Rate	30...(2)...80 ppm	N/A	N/A
AT-1 Therapy Delay	0...(5)...55 seconds	N/A	N/A

Appendix A

Connector Compatibility

Tachos DR - Atrial Tx ICDs are indicated for use only with commercially available bipolar ICD lead systems or other lead systems with which it has been tested. The separate atrial pacing/sensing lead may be any commercially available pacing lead. The Tachos DR - Atrial Tx is mechanically compatible with:

- IS-1 sensing/pacing lead connectors
- DF-1 defibrillation lead connectors.

The ICD has two IS-1 header ports and two DF-1 header ports.

Appendix B

Atrial Detection and Therapy Programming Recommendations

Parameter	Programming Suggestions
AF Zone	
AF Zone Detection	300 ms
AF Zone Therapy	HF Burst & Shocks
Number of Atrial HF Burst Therapies	At least 5 bursts
Atrial HF Burst Duration	At least 6 seconds
Number of Atrial Shocks	2
AF Shock Energy: 1st Shock	At least (2 x atrial DFT) or (atrial DFT + 5 joules)
2nd Shock	At least (10 J + 1st shock energy) or (2 x atrial DFT)
AT-1 Zone	
AT-1 Zone Detection	350 ms
AT-1 Zone Therapy	ATP & Shocks
AT-1 Therapy Delay	15 seconds
Number of Atrial ATP Therapies	At least 5 bursts
Number of Atrial ATP Pulses	At least 8 pulses
Number of Atrial Shocks	2
AF Shock Energy: 1st Shock	At least (2 x atrial DFT) or (atrial DFT + 5 joules)
2nd Shock	At least (10 J + 1st shock energy) or (2 x atrial DFT)
Advanced Sensing	
A Blank-V Pace	40 ms
A Blank-V Sense	30 ms
Advanced Therapy	
Atrial Max Shock Energy	30 J

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